INNOVATION AND PATENT LAW

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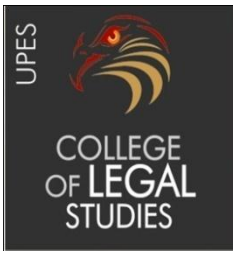

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CERTIFICATE

This is to Certify that the research work entitled **" Innovation and Patent Law"** is work done by Bharti Chhabra Under my guidance and Supervision for the partial fulfilment of the requirement of B.B.A. LLB(Hons) degree at college of Legal Studies, University of Petroleum and Energy Studies, Dehradun.

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DECLARATION

I declare that the dissertation entitled **"Innovation and Patent Law"** is the outcome of my own work conducted under the supervision of Prof Charu Srivastva at College of Legal Studies, University of Petroleum and Energy Studies, Dehradun.

I declare that the dissertation comprises only of my original work and due acknowledgement has been made in the text to all other material used.

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Date

Contents

List Of Abbreviation

IPR- Intellectual Property Rights

WIPO- World Intellectual Property Organisation

WTO- World Trade Organisation

TRIPS- Trade Related Intellectual Property System

Sec.- section

Vol.-Volume

SCC- Supreme Court Cases

SC- Supreme Court

V.- versus

R&D- Research and Development

GATT- General Agreement of Trade and Tariff

U.S.- United States

U.K.- United Kingdom

USPTO- United State Patent and Trademark Ofiice

Ch.- Chapter

Co.- Company

IP- Intellectual Property

Para.- Paragraph

PLT- Patent Law Treaty

Table of Cases

Acknowledgment

It is a great pleasure for me to put on records my appreciation and gratitude towards Prof. Charu Srivastava for his immense support and encouragement all through the preparation of this paper and for their valuable support and suggestions for the improvement and editing of project.

Last but not the least, I would like to thank all the friends and others who directly or indirectly helped me in completing my project report.

Chapter 1: Introduction

The concept of property can be retraced to early periods with the imitation of cultivation of agriculture land, land was recognised as a form of property. Urbanisation bought in material growth and specialisation in different field. As man began to excavate and they come up with new and novel discoveries. In predynastic period, tools and weapons were used regularly. As science progressed, the need was felt for proper issue of knowledge. This called for some form protection to creator. Early innovation was the basis for growth of modern technology. Different modern technology bought revolution in different field. Even in the modern times the companies are striving to be different and own modern technology. Such, strive for being different and being modern has lead to lot of investment in the research and development by respective company. And a lot of money is spent to modernise the technology. Though the modernization of technology is still growing at fast pace as it is required to meet the increased challenges and high competition. It has been recognized world over that the power of an enterprise or a company to capture the market, depend largely on developing innovative technologies. The development of new innovation and business depend not only upon the scientist, engineers and others, but also on investment on research and development. Currently, protection of innovation resulting from R&D program has presumed great importance in modern times. Accomplishment in inventing and guarantying protection by way of patents is based on steering the advancement diligently and efficiently. Broadly there are three kinds of property. They are-

1. Movable property- the property which is not fixed to anything such as land
2. Immovable property- the property which is permanently fixed to something
3. Intellectual property- it is another kind of property derived from activities of the human intellect.

In recent times, technological innovations are becoming multi disciplinary in nature. Increasing R&D directing innovation towards finding appropriate solution for the growing complicated technical problems. For industrial progress of a country, continuous development of new technologies is also very essential. So with increase in the industrialisation , IRP has assumed a vital role throughout the world in recent past. Intellectual property which was mainly subject matter of the World Intellectual Property organisation (WIPO) has become a part of the World Trade Organisation(WTO) regime in

1995. The TRIPS agreement of the WTO treaty evolved minimum standard for the protection of intellectual property for member states to incorporate in their municipal laws.[1]

So, what is Intellectual Property?

IP is referred to as the novel product of human intellectual effort.[2] The term property is used to describe intellectual product which denotes the existence of right and remedies in respect of the property and unjustifiable interference. It also involves a degree of control exercised by the right holder, that is, control over invention. Presently, IP protection operates as other forms of property. IP is concerned with dealing with intellectual products, generally with the consent of right holder. Property right affirm private interest, significant among this interest is the interest of the owner to enjoy his property. These right are curtailed in rare circumstances. The main motivation of its protection is to encourage and reward creativity. Intellectual property is usually divided into two braches-

1. Copyright- it subsist in original literary, dramactic, musical and artistic works. 2. Cinematograph films 3. Sound recording.
2. Industrial Property- it is kind of intellectual property and relates to creation of mind. Such conception is invention and industrial designs. Invention is solution to technological, scientific problem whereas industrial design are aesthetic creation determine the appearance of industrial product. Apart from this, industrial property includes trademarks, service mark, layout-design of integrated circuits, commercial name and designation as well as geographical indication and protection against unfair competition.

Thus, Intellectual property includes patents, design, trademarks, copyright, confidential information and industrial know-how. This property of whatever species is in the nature of intangible incorporate property.[3] In each case it consists of bundle of right in relation to certain object created by the owner. In other word, the use of property to describe intellectual products implies the existence of right, control and unwarranted interference. They can be bought and sold, mortgaged and licensed, just like any other property. In the case of patent

[1] Ahuja V.K., Law Relating to Intllectual Property Rights, 1st edition.
[2] Charlotte Waelde, Graeme Laurie, Abbe Brown, Smita Kheria, Jane Cornwell, Contemporary Intellectual Property Law and Policy, Oxford
[3] P. Narayana, Intellectual Property law, 3rd edition, Eastern Law house, PP2

the property consists of the exclusive right to use the invention patented, to grant license to others to exercise that right or sell that right to a third person. In case of industrial design the property consists in the exclusion right to apply the design registered under the particular. Similarly, copy right involve the protection of literary dramatic, sound recording etc. all such right is creation of a statute. All the country has their particular statue dealing with the respective rights. Thus, they are territorial in nature.

Territorial nature means that an intellectual property right is only effective in the territory of the state granting the right. But now various international conventions exist which assist the applicant to make multiple simultaneous application in several countries. The content of a particular intellectual property right vary from country to country. Despite the existence of international convention attempting to standardise intellectual property laws, differences exist in the domestic laws of the parties to the convention. These differences relate to provision concerning the creation or infringement of a particular intellectual property right or to the legal system within which the right is enforced.[4]

Further, intellectual Property rights are exclusive right. It implies that the intellectual property right are negative in nature, because the owner is given the right to exclude others. Intellectual property lacks physical form that defines its boundaries, yet this right are regarded as in rem proprietary rights.[5] For example under patent law only the inventor has the right to exclusive exploited his invention. Secondly, the phase exclusive right means that the owner of the intellectual property right is the only person who can exploit the right. For example- the patentee is the only person who can make the patented product, offer it for sale, dispose it of or can use it by way of trade. In other words, intellectual property right give rise to a legal monopoly. Whether monopolies are good or bad is the subject matter of debate. At present intellectual property legislation contain built in safe guards to ensure that a balance is struck between the rights of the intellectual property owner and free competition. Some of these safeguards require the owner to pay renewal fees regularly. Other requires the owner to make effective use of intellectual property right. Failure to exploit result in compulsory licensing. Further, the statue provides for the right to be declared invalid in certain instances, so unlike real property and tangible personal property, intellectual property rights are valuable to destruction.

[4] Helen Norman. Irl, oxford

[5] Jus in re proprai means the right of enjoyment that is incident to full ownership of property. In other, word it signify full ownership itself.

Justifying Intellectual Property Rights

Moral Interest

Intellectual property right are produced by the efforts of people who have contributed from within themselves to the creation of the new entity and so, it is thought IP reflects a moral connection between the property and its creators. Another, common moral reason to protect IP is because it would be unjust for others to benefit from a creator's time, efforts and expenditure if it were possible simply to copy new intellectual products without fear of reprisal.

Social Interest

Many social benefit can arise from the IP. Indeed, it is precisely this argument that is advanced by the pharmaceutical companies: 'give us Protection for our drugs and we will have an incentive to produce them; deprive us of that protection and the incentive is gone.' But if IP is protected strongly social interest will be compromised. For example, their will be no healthy competition in the market.

Economic Interest

The economic interest of the producer of IP and his competitiors and his customer will be affected when the property is exploited in the market place.

Need for IPR

1. IPR are the key elements needed to maintain the competitive dege of any industry. It impart success to an entity by providing exclusive markets
2. The cost of R&D in developing new products and process is rising sharply, hence there is need to increase and accelerate the extent of protection of IPRs to get return of investment and to reduce element of risk and uncertainty.[6]
3. Intellectual property is emerging as wealth of nation and are described as global currency.

[6] Dr. R. Radhakrishnan, Dr. S. Balasubramanian, Intellectual Property Rights, text and cases, first edition, pp 3

4. IPR provide incentive to investor for further research and investment in R&D, which lead to further invention and in return bring economic growth and social benefits.

Innovation and Intellectual Property Rights

There is no precise definition of innovation available. It is a abstract concept defining a situation which cannot be explained in the terms of known things. The term does not have a specific meaning and vary according to as defined under the statue of a country. In other words, the term innovation does not have a specific meaning or substantial essentials which determine a particular thing constitute innovation. It is subjective term and has been granted different meaning under statues by the country all over the world. In simple words, it can be defined as the creation of a object or a process which has been not in existence before.

Companies all over the world are striving for the innovation in their respective field. For such, innovation they are investing lot of money. After investing so much of time, efforts and money they seek protection under the statute. Innovation is protected under Patent which is one of the kind of the intellectual property right. In other words, a patent is a form of intellectual property right granted and protected by the law. The word patent refers to a monopoly right over an invention. Not all invention is patentable nor is essential to protect invention solely through patents. The final product from an invention may be protected though other form of intellectual property rights.

The law of patent is synergy of science and law. The law of patent is a legal framework which establishes a system which supports and encourages technological innovation and promotes economic development. It includes a conglomeration of legislation, judicial decision, patent specification, scientific documents, legal opinions and everything which can be covered under state of art

Definition of Patent

The term patent originated from the latin term **literae Patentes (** letters patent) which means open letter. In Britain, it was so called as they were open and not sealed, bearing the great seal at the bottom and a proclamation from the sovereign to the subject. The grant of patent was matter of sovereign grace. Latter patent were impressively worded documents which captured the sprit of Austin's command theory. The latter patent would strictly command all the subjects that they shall not, during the continuance of the term of the patent, make use of or put in practice the said invention. Any disobedience was visited by sanction in the form of

penalties as may be justly inflicted on such offenders for their contempt of the Royal command, apart from damages claimed by the patentee.[7]

A patent may be defined as a grant by state of exclusive rights for limited time in respect of a new and useful invention.

Exclusionary Right

The right given by the patent do not include right to practice the invention only but also to exclude others from doing so. The patentee's freedom to use his invention may be limited by legislation or regulations.[8] The privilege offered is negative all right reject others from utilizing the topic of the patent.

Property Right

A patent is piece of property and is valuable one although, intangible property but is dealt in the same sense as tangible property. The Indian Patent Act, Patent Act, 1977 regards patent as movable property and provides that the rule of la applicable to the ownership and devolution of movable property shall apply in relation to patents.[9]. Patents confer Jus in re Propria which grants full ownership over intangible thing.

Time Bound right

A patent is granted for limited period of time. In any case, no patent can go on indefinitely. It is a point that is central towards the whole concept of patents that the exclusive rights are granted only for restricted time period and the general public is free to utilize the invention on its expiry. The act provide for 20 year of protection. Upon the expiry of patent, any person will be able to exploit the invention

Patent as monopoly Right

Patent is sort of monopoly granted by the state but it does not strictly fall within the definition of monopoly. A monopoly generally refer to privilege granted to particular company whereby the public at large is restrained from manufacturing or trading with the subject matter of the privilege which they had before. Law imposes a duty on the patentee to supply information

[7] Feroz Ali Khader, The Law of Patents-with special focus on pharmaceuticals in India, Lexis Nexis butterworths
[8] Philip W. Grubb, Peter R. Thomsen, patents for chemicals, pharmaceuticals and biotechnology, 5th editon, oxford
[9] Patent act, 1970, S.50

on patent. Monopoly right is granted subject to two condition-: firstly, to ensure that the monopoly granted by the patent does not extends than the invention which the applicant for the patent has made. Secondly, to ensure that the public shall, in return for the grant of patent be put in full possession of the way to carry out the invention in order that, after the patent has expired they may enjoy to the full benefit of that invention.[10]

History of patent law[11]

The modern patent law is said to have originated in vainnce in 1474 when patent was granted as a means to attract skilled merchants, there exists some evidence to show the prevelance of patent like grant prior to that period in the United kingdom.[12] The origin of patent law can be traced back to law and practice on patent in UK.

The first major patent legislation in India was introduced by the British in 1911 to protect the interest of investors. Before the introduction of Indian Patent and Design Act, 1911 there were series of statue which conferred exclusive privileges namely Act VI of 1856, Act XV of 1859, protection of Invention Act, 1883 etc. due to various lacuna in the these act, Indian Patent and Design act was passed. Since implementation of this act, legal system has changed. The socio-economic and political changes in country required a new set of law.

Tek chand Committee

In 1948, the Government appointed a patent Enquiry Committee under the chairmanship of Dr. Bakshi Tek Chand, a retired judge of Lahore High Court to review the working of Indian Patent and Designs Act, 1911 and to see whether the Indian Patent system was in line with national interest. The final report of the committee was submitted in 1950. Based on the recommendation of the committee and on Patent act, 1949 of UK, the Patent Bill was introduced in Lok Sabha. But the bill lapsed.

Ayyanger Committee

Another attempt was made by government in 1957 and a nanother committe was appointed under the chairmanship of Justice N rajagopla Aayanger to study and recommend changes to

[10] Vidal Dyes Syndicate Ltd Vs. Levinstein Ltd, (1912) 29 RPC 245
[11] Khader Ali Feroz, The law of Patents-with a special focus on Pharmceuticals in India, Lexis Nexis Butterworths Wahwa.
[12] Supara 12

patent law in India. [13] Both the Tek chand and Ayyanger committee found that vast majority of patent were held by foreigners and most of them not worked in India. The ayyanger committee recommended the retention of the patent system despite its shortcoming. The recommendation of Ayyanger committee, particularly the recommendation on patent for food, medicine, or drug along with other changes was introduced as Patent Bill, 1965. A Joint parliamentary committee studied the bill and submitted its report along with certain amendment to Lok sabha. The amended bill lapsed in Lok sabha on account of dissolution. The bill was again introduced in 1967 with certain amendments. This time bill was passed and received the Presidential assent. The patent rule were published in November 1971. The act and rule come into force on 20th April 1972.

Patent Act, 1970

Presently, the patent is governed by the patent act, 1970. The act abolished product patent for food, medicine or drug which was granted under 1911 act. under this act for the first time, a distinction between process and product patent was introduced. The act also contained long list of invention which are not patentable. the act has so far seen three major amendments which were done as part of the exercise to conform the Indian patent laws to the obligation under the TRIPS agreement of the WTO.

Patent (amendment) Act, 2005

The patent bill 2003 introduced to bring amendment to the patent act, but the bill lapse. As the deadline for compiling with the TRIPS agreement was nearing, government introduced Patent ordinance 2004. The ordinance was an improvement on the patent amendment bill, 2003. The ordinance was succeeded by the Patent Amendment bill 2005.

The amendment act come into force with retrospective effect from 1st jan 2005. The salient feature of the amendment include- omission of section 5 and introduction of product patent for pharmaceutical, omission of Ch IVA dealing with EMR. Provision for publication of the application of patent introduced; opposition cab be made at the time of publication on the same ground on which the grant of patent can be opposed, opposition could be made within 12 month from the date of grant of patent, advertisement and notification in the official gazette replaced by publication in the official journal.

[13] Justice N Rajagopla Ayyangar, Report on the Revision of the Patent Laws, September 1959.

Indian patent act has not been effective in protecting the invention. Which is the backbone of the patent law. As the patent law come into play when an protection is seeker for the protection for invention. invention is the driving force of the market, every industry whatever nature, is trying invention in one way or the other. As the invention help they become the market leader. Whether their invention can be protected under Patent act depends upon the definition of the invention under the act.

Chapter 2 of the dissertation is aims at analysing the definition of Indian law with that of the US and UK law. As both the country have invention friendly law and US has the highest number of the patent all over the world, which is one of the driving force of its economy.

Nanotechnology is one of the emerging technology, researcher, students, scientists around the world are engaged in the developing one or the other form of nanotechnology. Nanotechnology is the application of technology at the nano scale and invention under nanotechnology is small in size of existing technology. So, claiming patent for nanotechnology is not easy.

There are various issue involved in the patenting of nanotechnology, like it being a multi disciplinary field, no specification definition etc, beside satisfying the basic requirement of the novelty, non-obviousness and industrial application. Indian patent act, has granted very few patent to nanotechnology whereas U.S. has grnated highest number of the patent to nanotechnology. Chapter-3 of the dissertation is aims at analysisng the hurdles in patenting of nanotechnology.

Biotechnology is another industry which is growing at very fast pace. It is involved in manufacturing of the food item, medicine. The patenting of the invention under the biotechnology has been one of the controversial issue all the world. Many group have opposed the patenting of the invention under biotechnology.

Patenting under biotechnology is opposed as it involve life forms. In other words, most of the invention under biotechnology concerned with life forms like DNA, genes, transgenic animal, plant etc. so, before granting patent the issue of moral and ethics has to be settled, then the issue of discovery Vs. Invention, then the test of basic requirement under the patent act i.e. of novelty, non-obviousness, industrial application etc, which create a another hindrance for patenting of biotechnology. Hence, chapter 4 of the

dissertation aims at analysing the challenges in patenting of biotechnology in India as compared to that of US.

The IPR all over the world is governed by the some international bodies, agreement, treaties which aim at promoting and lying down the minimum standards for the IPR, for the member countries to WTO. So, chapter 5 aims at analysing the international framework governing the IPR with special emphasis on patent.

Hence, the dissertation aim at analysing the concept of Innovation and the challenges of patenting of Innovation in the emerging industries i.e. nanotechnology and biotechnology and the international framework, governing the IPR with special emphasis on patent law.

Chapter 2: Meaning and understanding of Innovation

Innovation has become the backbone of the market. Every company is trying to innovate one thing or the other, so as to become the market leader. Innovation helps a company to gain competitive edge. Lot of time, efforts and intellectual labour are invested for an innovation. But what is innovation. There is no precise definition of innovation that is available. It has been defined differently by the different country. The definition of innovation is significant as before it is granted protection, it should be clear what constitute the innovation. In this chapter an attempt is made to understand the definition of Innovation under the US, UK and Indian Law.

U.S. law

The United States Patent and trademark office agency in United States issues the patent for invention and for trademark. The U.S. patent and trademark office issue different kind of patent for different subject matter. United States has highest number of patent. A patent is generally granted for Inventions and the definition of the invention varies from country to country. Under US law patent is granted for the invention as well as for the discoveries. As per section 35 USC 101 " whoever invents or discovers any new and useful process, machine, manufacture or composite of matter, or any new or improvement thereof, may obtain a patent therefore, subject to the condition and requirement of this titles."

So, as per section 35 an invention or discovery both can be granted patent. Even the definition is wide enough to include the improvement to the existing subject matter. Thereby, increasing the scope of claiming the patent but such patent will be granted subject to the condition as stipulated.

Utility Patent

This type of patent is issued for invention new and useful process, machine, manufacture or composite of material or new of useful improvement thereof, it permit its owner to exclude others from making, using or selling the invention for period of twenty year from the date of filing of patent. As per section 101 of title 35 states that whoever invents or discovers any

new and useful improvement thereof, can seek a patent.[14] The categories include a new use of known process, machine, manufacture, composite of matter or material.[15] A process is an act or a series of acts that produces a desired result.[16]

In the case of Cochrane V. Deener, the S.C. set forth definition of process- A process is a mode of treatment of certain material to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.[17] A machine is a device that has relatively movable parts and that perform a useful operation. An article of manufacture is generally defined as any tangible object, other than a machine or composition of matter that is man-made and not found in substantially the same in form in nature.[18]

Invention should be useful in order to be patentable. In other words it should have utility.

Utility

Utility or useful means an invention should attain one of its intended functions. Intended function means machine, articles of manufacture and process meet the utility requirement of section 101 if they are minimally operable to perform as they were intended to perform. A novel product or process will meet the easily satisfied utility requirement of 35 U.S.C. 101 as long as it can be used to achieve at least one of the stated aims; it is not necessary that it accomplish all objective set forth in the specification.[19] Even if an invention merely imitates or simulates another invention, it is sufficient to satisfy the utility requirement of patentability.[20]

Novelty

Section 101 states that " whoever invents or discovers any new and useful" the utility requirement is met by applying section 102. Section 102 describe act of inventor or other, occurring before the making of invention by applicant or before the filing of a patent application.

[14] 35 U.S.C. 101(1994)
[15] 35 U.S.C. 100(1999)
[16] Michael A. Epstein, Epstein on Intellectual Property, fifth edition, Wolters Kluwer law & Business.
[17] 94 U.S. 780, 788
[18] Diamond Vs. Chakrabarty, 447 U.S. 303(1981)
[19] Ibid 16
[20] Juicy whip, Inc. Vs. organe Bang, Inc., 185 F.3d 1364, 1367.

Section 102(a)

As per section 102(a), an applicant is denied a patent if the subject matter of the invention as claimed was known or used by someone other than the inventor in the united states before the inventor's date of invention or if subject matter was patented or described in any printed publication by someone other than the inventor anywhere before the inventors date of invention.

Section 102(b)

As per section 102(b), an application for an invention is not to be granted a patent if subject matter of the claimed invention was publicly used or sale in the united states by anyone, including the inventor, more than one year before the effective date of filing of application or if subject matter claimed invention was patented by anyone, anywhere in the world, more than one year before the effective filing date of the U.S. application.[21]

Section 102(c)

As per section 102 if invention has been deserted the inventor cannot thereafter resurrect it for purpose of obtain patent protection. Abandonment can occur in number of ways like delay in filing a patent application, may intend to dedicate the invention to public or keep it as secret.

Section 102(e)

as per section 102(e) if another U.S. patent application that is filed before the applicant's effective filing date and either issues as a U.S. patent or is published under section 122 after the application effective filing date can be used to deny patent protection under section 102(e) even though no information concerning the earlier filed application was available to the public on the applicant's effective filing date.[22]

[21] Ibid 16
[22] Ibid 16

Section 102(f)

An inventor who did not invent the subject matter of the application is barred from obtaing a valid U.S. patent.

Section 102(g)

It is often referred to as the" interference provision" precludes patent protection to an applicant if someone other than the applicant made the applicant's claimed invention in the United states or In NAFTA or WTO.[23]

Non-obviousness

Section 103 of the 1952 Patent Act prevent an inventor from obtaining a patent if the difference between the subject matter attempted to be patented and the prior art are such that the subject matter as a whole would be obvious to one of the ordinary skill in the art.[24] In simple words, it should not be obvious for the person skilled in the art of subject matter for which the patent is claimed. The test for patentability under section 103 was enunciated by the Supreme court in the case of Graham V. John Deere Co.[25] , court ruled that the test for obviousness had three required elements:

1. The scope and content of prior art
2. The difference between the prior art and claim at issue
3. The level of ordinary skill in the art

Court further stated but did not mandated inquiry into so-called secondary considerations, only stating that they "might" be utilized to give light to the circumstances surrounding the origin of the subject-matter sought to be patented. As indicia of obviousness or non-obviouness, these inquires may have relevancy.

The federal court has since required that the secondary consideration be used as fourth factor when deciding the issue of obviousness.[26] The fourth inquiry involve examination of objective evidence of non-obviousness, including the commercial success of the invention,

[23] 35 U.S.C 102(g) (1999) provides
[24] 35 U.S.C. 103(a) (1994)
[25] 383 U.S. 1, 17(1966)
[26] Glaverbel Societe Anonyme Vs. North lake Mktg. & Supply Inc., 45 F. 3d 1550,1555

unexpected synergism, long left but unsolved need for the invention and the failure of others to develop the invention.[27]

The obviousness test is a flexible inquiry that accounts for inferences, creative step, and common sense that a person of ordinary skill in art would employ.[28]

Adequate Disclosure

In addition to meeting the novelty, utility and non-obviousness standards for patentability, an applicant is might not be granted patent unless he describe invention in patent application in such a manner so as to fulfil the requirement of adequate disclosure set forth in 35 U.S.C. 112. The description requirement compels the inventor to describe the claimed feature of the invention with particularity. The test under this provision is a consideration of whether the application actually discloses the particular devise with specificity as to the claimed features of the invention.[29]

Plant Patent

Title 35 applies to plant patents. in order to qualify as statutory subject matter, a variety of plant must be new and distinct, must reproduce asexually and must be found only in a cultivated state. The provision of 35 U.S.C 112 do not have to be complied with if specification includes as full and complete description as is reasonably possible.[30]

Design Patent

Design patent embrace the visual characteristics displayed by an object and relate to configuration, shape or surface ornamentation. The provision of title 35 apply to design patent. In general the requirement of design is same as that in India that is it must be new, original and or name.

[27] Ibid 16
[28] Supra 27
[29] O' Reilly Vs Morse, 56 U.S.
[30] 35 U.S.C. 162

U.K. Law

In U.K., many area of commercial law, the law of patent was shaped primarily by nineteenth century events and was a belated response to the industrial revolution. By amending the patent law many times finally the U.K. come up with Patent Act, 1977. As other law prevailing all over the world In U.K. as well the patent is granted for Invention. Different type of patent granted under the UK law is-

a. **Product by process claim**

   The U.K. has traditionally allowed this kind of alim whereby a product could be claimed by the reference to its process of manufacture rather than by its own technical feature.

b. **Selection patents**

   Mere existence of a substance is not fatal in terms of novelty the prior art must plant a flag at the specific spot of invention for example not only a susbtance's existence but perhaps also is structure, its function, its special qualities and the means to make it. useful in chemical and biotechnology industries.

Section1 (1) of the Patent act, 1977 states

A patent may be granted only for invention in respect of which the following condition are satisfied-

1. The invention is new
2. It involve inventive step
3. Capable of industrial application
4. The grant of patent for it not excluded by sub-section (2) and (3)

Novelty

Novelty has been defined under section 2 of the Patent Act, 1977. Section 2(1) of the 1977 act provides that " An invention shall be taken to be new if it does not form part of state of art. State of art has been defined under section 2(2) of the act. The definition under the section 2(2) is wide definition and state manner by which information about an invention about an invention might be disclosed.

Available to public does not require that the member of public have actual vision of the information, merely that they can access to the information, either freely or on payment of fees. Allowing the public an opportunity to examine the details of an invention in circumstances where a skilled person would become aware of the core technical features of the invention would amount to public disclosure.[31] If an invention already exist in the state of the art then the patent application or invention is considered as anticipated. Section 2(4) of patent act, 1977 provide for what does not constitute the state of art-:

1. Disclosure about the invention which is made in breach of confidence or unlawfully
2. Disclosures made by the inventor at recognised international exhibition, can be excluded from the state of art provided patent is applied within six months of the disclosure in question.

The policy underlying the novelty requirement is to ensure that matter which is already in the public domain is not brought once again under private monopoly control, and to protect parties who have been using a product or process publicly.[32]

Inventive Step

Inventive step is also referred to as non-obviousness. Inventive step has been defined under section 3 of the act which states-

" an invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regards to any matter which form part of state of art by virture of section 2(2)."

The idea of person skilled in the art is a device used by the intellectual property office and courts to access the merits of any given innovation. He is ordinary member of their field who is aware of everything in the state of art. [33]

[31] Miliken Denmark AS vs Walk off Mats ltd and another, [1996] FSR 292
[32] Charlotte waelde, Graeme Laurie, Abbe Brown, Smita Kheria, Jane Cornwell, contemporary Intellectual Property, Law and policy, oxford publication, 3rd edition.
[33] Supra 32

Test of obviousness

In the case of Windsurfing International Inc Vs. Tabur Marine (GB) Ltd[34] court stated that the obviousness is to be tested by asking what would have been obvious to a person skilled in the particular art at time of priority date of the patent. Further, a four-step process ws laid down by the court-

a. Identify the 'inventive concept' embodies in the patent
b. Impute to a normally skilled but unimaginative addressee what was common general knowledge in the art at priority date
c. Identify the difference if any, between the matter cited as part of the state of the art and the alleged invention.
d. Decide whether those differences, viewed without any knowledge of the alleged invention, constitute steps which would have been obvious to the skilled man or whether they require a degree of invention.

The inventive concept has to decided from case to case basis considering the prior art.

These question were reformulated by the court of appeal in Pozzoli SPA vs BDMO SA[35]. In this case the court stated that the windsurfing and pozzil are to be read together.

The Windsurfing/ Pozzaoli approach

1. (a) identify the notional of person skilled in the art
   (b) identify the relevant common general knowledge of that person

2. Identify the inventive concept of the claim in question or if that cannot be readily be done, construe it.
3. Identify what, if any, differences exist between the matter cited as forming the part of the state of art and the inventive concept of the claim and the claim as constructed.
4. Viewed without any knowledge of the alleged invention as claimed, do those difference constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

[34] 1985, RPC 59(CA)
[35] 2007, FSR 37

In the case of Generic(UK) Ltd and other V H Lundbeck[36], court further laid down factors to be considered to determine obviousness

1. What was the problem which the patented development addressed?
2. How long problem had that problem existed
3. How significant was problem seen to be?
4. How widely known was the problem and how many were likely to be seeking a solution
5. What prior art would have been likely to be known to all or most of those who would have been expected to be involved in finding a solution?
6. What other solution were put forward in the period leading up to rhe publication of the patentee's development?
7. To what extent were there factors which would have held back the exploitation of the solution even if it was technically obvious
8. How ell patentees development being received?

This is not an exhaustive list but it is a helpful guide which may point either towards or away from inventiveness.

Industrial applicability

The final condition for patentability is to ensure that of the industrial or technical nature of invention. Section 4(1) states that an invention shall be taken to be capable of industrial application if it is capable of being made or used in any kind of industry, including agriculture.

The requirement is only that of the invention is capable of being use in industry or agriculture, no actual evidence of effective use is required.

Under UK law following subject matter are not considered patentable

1. Discoveries, scientific theories and mathematical methods
2. Aesthetic creations

   Example of aesthetic creation which are excluded include literary, dramatic, musical and artistic works.

[36] 2009, UKHL 12

3. Schemes, rules and methods for performing mental acts, playing games or doing business and programs for computer
4. Presentation of information

   This concern exclusion of the content of information. No claim will be sustained if it relates solely to the expression of information or the conveyance of the meaning or decision on where and how to display information. Patent law is not in business of giving protection to pretty pictures, tv images, radio signals, books, sound, codes or symbols which derive their value from the meaning they convey to human being.
5. Method of treatment of the human or animal body

   They are excluded so as not to interfere in the matter of public health, surgery.
6. Morality, order public and plant varieties.

Indian Law

Under Indian law the patent is granted under Patent Act, 1970. According to section 2(1)(m) patent means a patent for invention granted under the act. Under the present Indian Patent Act, 1970 patent can be granted for both the product and the process, if the invention satisfy the patentability requirement. Section 2(j) define invention as " Invention means a new product or process involving an inventive step and capable of industrial application.

Novelty

New invention means any invention or technology which has not been anticipated by the publication in any document or used in the country or elsewhere in the world before the date of filling of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the art.[37]

In order to be patentable invention should be new or novel.

[37] Section 2(1)(1), patent Act, 1970

New or novel

The patent act, 1970 require an invention to be patentable it should be novel. Novelty is determined considering the knowledge available everywhere in the world.

The determination of novelty of an invention consists of considering two aspects- the invention claimed for protection and prior art information available in concerned field.[38] An invention is considered new if it is not anticipated by prior art. In other words, on date of filing of patent application, it should not form part of the state of art.[39]

Prior art means the total complete knowledge available to public before the priority date of invention. The knowledge of an invention in order to be considered as relevant prior art should satisfy any one or more of the following[40]-:

1. By the description of the invention in a published writing or document or in any other tangible form
2. By description of invention in spoken words uttered in public, such a disclosure is known as oral disclosure
3. By the use of the invention in public or by putting the public in position where any member of public may access to it.

In other words the document must have been not being published or made available to public prior to the date of filing of the application or priority date whichever is earlier.

In *Bishwanath Prasad Radhey Shyam Vs. Hindustan Metal Industries*[41], the supreme court observed the fundamental principle of patent law is that a patent should be granted only for invention which are new and useful. In other word, it must have novelty and utility. It is essential for the validity of patent that it must be inventors own discovery as opposed to mere verification of what was already known before the date of patent.

The court further stated that whether alleged invention involved inventive step was a mixed question of fact and law, depending largely of position of the case.

[38] N R subbaram, patent law practices and procedure, 2nd edition, 2007
[39] Law relating to intellectual property right
[40] Supra 38
[41] (1979) 2 SCC 511

In the case of *Blakey and Co Vs Lathern and Co*[42] court stated that in order to be patentable the claim must involve invention over what is old.

Thus, in order to establish the novelty of an invention disclosed in the application for patent, there should not be any prior disclosure of exact invention anywhere in the world, before the date of application or priority date whichever is earlier.

Inventive Step (Non-obviousness)

Inventive step means the invention involve technical advances as compared to the existing knowledge or having economic significance or both and that make invention non-obvious for person skilled in the art.[43]

The question involved while determining inventive step is whether or not an invention would have been obvious to a person skilled in the art is difficult to determine. The reason for including such factor is the patent should not be granted to invention which is already part of prior art or is obvious for a person ordinarily skilled in the field in which patent is claimed. The person ordinarily skilled in the art is presumed to be ordinary person who is aware of the general common knowledge of relevant field.[44]

The difference between determining novelty and inventive step lies in the fact that the question of inventive step aries only when the condition of novelty is proved. Moreover, as compared to novelty, to determine non-obviousness it is determined with respect to person skilled in the field.

Following aspect are to be considered while determine the inventive step-:

a. The problem to be solved
b. The solution to that problem and
c. The result guaranteed by the application of that solution.

If the problem is obvious or common, then the originality of the solution is considered. If no inventive step in the solution claimed the question will arise as to whether or not the result is obvious or whether it is surprising either by its nature or by its extent.

[42] (1889) 6 RPC 184 (CA)
[43] S. 2(1)(ja), Patent Act, 1970
[44] Ibid 38

Another way to determine obviousness of an invention is to considered the factor that whether an invention is finding out something which is not known for person ordinarily skilled in the prior art to the disclosure made in the application.

So, the question which is considered is " whether a person skilled in the state of the art when application is filed can carry out the invention. If answer is yes then invention is obvious.[45]

Thus, to be patentable, an invention should not be obvious for the person reasonably skilled in the art. The term obvious means that which does not goes beyond the normal progress of technology but merely follows plainly and logically from the prior art i.e. something which does not involve exercise of any skill or ability beyond that to be expected of person skilled in the art.[46]

Industrial application (utility)

Utility means the invention is capable of being made or used in the industry.[47] In simple words, invention should be capable of being used in the industry. Invention should not be theoretical. It should be able to carry out in practice and should be useful to society. Quantum of usefulness is not relevant.

[45] Ibid 38
[46] Rama Sarma, Intellectual Property Laws, Vol 1, edition 2007, Wadhwa Nagpur.
[47] Sec 2(1)(ac), Patent Act, 1970.

Comparative Analysis

The definition of the term innovation is of significant as increased the application of law on the different inventive technology and make them patentable. patent is granted for innovation. So, before a patent is granted there is need for what constitute the innovation. The term innovation has been defined differently by the different country according to their own convince. There is no specific definition of the innovation. Patent is vital for any company, as it provide it with exclusive right of exploitation.

The term innovation has been defined under the US law under 35 USC 101

" whoever invents or discovers any new and useful process, machine, manufacture or composite of matter, or any new or improvement thereof, may obtain a patent therefore, subject to the condition and requirement of this titles".

As per the definition following invention are patentable-

1. Discovery
2. Invention
3. New or improvement to already existing process, machine, manufacture or composite of matter
4. All such will be patentable only when other requirement under the act are fulfilled..

Hence, the definition of the innovation under the US law is much wider as it include discovery and improvement to already existing product, composite of matter.

Under India law the term Invention[48] has been defined as new product or process involving an inventive step and capable of industrial application. Inventive step means a feature of an invention that involve technical advance as compared to existing knowledge.

As per definition

Under the UK law invention has been defined under section 1(1) which means

1. The invention is new
2. It involve inventive step
3. Capable of industrial application

[48] Section 2(j) patent act, 1970

4. The grant of patent for it not excluded by sub-section (2) and (3)

So, the definition under the US law is much wider as compared to that of the Indian law and the UK law. As the definition under the US act, include discovery and improvement of already existing product or process.

Whereas, under Indian and UK law both the discovery and improvement are excluded from patentable subject matter. Section 3(d) of the Indian, patent act exclude discovery and improvement to already existing product or process are also excluded under the same section

Such product or process will only be granted patent when there is improved efficiency. What is efficiency has not been defined under the act. it has been left to the decision of the court to determine what constitute efficacy. Thus, there is vagueness under the act which make it difficult to seek patent. The definition of invention under the UK and Indian law more or less the same.

Hence, the definition under the US law is much wider tas compared to Indian and UK law, making it industry friendly. Such a wider definition give a wider scope to seek protection under the patent act which not only encourage invenstemt in R&D but also encourage the inventor.

Moreover, further requisites of the novelty, non-obviousness, industrial application, are similar in all the country. But the degree of rigidness varies. US have more of relaxed system as that to UK and Indian law.

As in US different test has been laid down to determine each of the Novelty, non-obviousness, industrial application.

Chapter 3:-Challenges in the Patenting of Nano-Technology

Introduction

Scientist in their respective field has been working day and night to bring changes in the already existing technology. They want to break all the limits set forth and want to bring a revolution in the already existing set of technology and information. This revolution, will have no human causalities but will impact every aspect of the human life. Such a revolution is changes in the technology on which human being is dependent. One of the emerging field of the science and technology is the nanotechnology. It is kind of revolution in the already existing technology and scientist all over the world are working on it. It is one of the emerging area in technology. The emergence of the nanotechnology can be traced back to the 1959, when Richard Feynman presented his talk there's plenty of room at the bottom to American Physical Society at California institute and initiated, the field of nanotechnology.

So, what is nanotechnology? There is no proper definition of the Nanotechnology In simple words it is any technology on nanoscale and which has an application in the real world. Most definition revolve around, it is science and technology of small things particular things which are less than 100nm. It involves manipulating the material at the molecular level.[49] In other words, Nanotechnology is the engineering of matter at the scale of atoms and molecules where size is measured in billionth of a meter (one nanometer= one-billionth of a meter).[50] Nanotechnology uses a basic unit of measure called a "nanometer" (nm) derived from the Greek word for midget. A nanometer is a billionth part (10-9) of a meter, with each nm being only three to five atoms wide.[51] Nanotechnology is the end-result of scientific development and ability to manipulate at smaller level. Just for example computer have gone from bulky computer to handy notebook. Size is everything in nanotechnology. As its name itself depict it is nano in size. With the passage of time the utility of nanotechnology has increased. It has become a multi-disciplinary field. Meaning thereby has an influence over the different areas from science to fashion.

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[49] What is nanotechnology, *Lynn Rathbun*, *Cornell*, *Nancy Heally*, *Georgia Tech available at* http://www.nnin.org/news-events/spotlights/what-nanotechnology, accessed on 3-1-2015

[50]Patenting of nanotechnology invention:issues and challenges, singh and associates, Priyanka Rashtogi, available at , http://www.lexology.com/library/detail.aspx?g=7025304d-89d2-4927-8c2e-c38a70164475

[51]Patenting Nanotechnology: Expolring the Challenges, http://www.wipo.int/wipo_magazine/en/2011/02/article_0009.html, Accesed on 3-1-2015

Application of Nanotechnology

At present nanotechnology is used in different field. Some of the real life example are-

1. **Medicine**

   Nanotechnology is being used to make new array of medical and biotechnology tools so that they are cheaper, safer and easy to administer. For example gold particle can be used to detect early-stage Alzheimer's disease.[52]

2. **Solar cells**

   Companies are developing solar cell which are much cheaper than the conventional solar cell and can be manufactured at a lower cost.[53]

3. **Sporting goods**

   Nanotechnology is being used to increase the strength of the rackets, filling any imperfections in club shaft materials and reducing the rate at which air leaks from tennis balls.[54]

4. **Environmental use**

   Nanotechnology is used to build lighter cars and machinery which is fuel efficient and uses alternative fuel. It is also used for water cleaning and air cleaning purposes.[55]

[52] Benefits and application, http://www.nano.gov/you/nanotechnology-benefits, last acceesed on 3-1-2015
[53] Nanotechnology in solar cells, http://www.understandingnano.com/solarcells.html, last accessed on 3-1-2015
[54] http://www.understandingnano.com/nanotech-applications.html, last accessed on 26-12-2014
[55] Supara 52

Intellectual property Rights and Nanotechnology

What is worth copying is prima facie worth protecting.[56] Is the genies of the intellectual property rights. Intellectual property right refer to the creation of mind. It is a legal right conferred by the special legislature of a country. There right refer to the property that is creation of mind i.e. invention, literary and artistic works, symbols, names, images and designs. Scientist, developers are indulging in the development of one or the other form of technology and a huge amount of money is invested in developing the new technologies. Companies are investing lot of money in their respective research and develop to develop new product or technologies to become a market leader. Hence, intellectual property right play a significant role in protecting the investment and time and effort of the scientist or artist. In other words, intellectual property rights –

1. Provide incentive to individual for new creation
2. Provide recognition to the inventor.
3. Ensure material award for intellectual property.

It can be divided into two categories-;

1. Copyright which include literary and artistic work
2. Industrial property which include invention (patent), trademarks, industrial design and geographical indication.[57]

Industrial property is omnipresent. It includes all the technological invention. Such invention can be protected under the Intellectual property right, Patent. The word "Patent" is derived from the Latin "Patere" meaning to "open up". But with time the meaning of the word patent has changed. A patent is the right granted to the owner to stop others from making, using or selling the invention. In other words, a patent is a monopoly right granted to the owner of the invention to make, use and sell the patented invention for a limited time period. In other words, it refer to a grant of privilege, property or authority made by the government or sovereign of the country to one or more individuals.

[56] Paterson, in University of London V university of tutorial Process ltd, 1916 (2) Ch. 601
[57] Justice Yatinder Singh, Cyber Laws, fifth edition, universal Law Publishing Co.,

Hence, the invention under the nanotechnology can be granted patented if it satisfy the per-requisites. But granting patent to an invention under the nanotechnology is not an easy task beside per-requisites there are many other hurdle on account of which patent can't be granted to an invention under the patent law.

It is an emerge gent field people from all over the world are running to get their innovation patented. US has highest number of patent in the field of nanotechnology followed by Japan and Germany. China is also encouraging the patent in nanotechnology and will soon become a leader in the patenting of nanotechnology. In India, there has been increase in the patenting activity after the introduction of the product patent and the many granting has been granted by the patent office from thereon. But in India the patent office has granted only sixty four patents in the field of the nanotechnology. In theory patent law has been passed to protect the innovation. But in practicality it is applied different in different context and it does not fit all the technology every time. Hence, there is always a need to amend the patent law.

Also observed by the standing committee on the law of patent of the WIPO, 'the patent system constantly faces the question whether and how it can adapt itself to new technology".[58]

Nanotechnology which deals with the matter of 100nm and below create a number of problem on account of multi-disciplinary field, cross-sector application etc which create a problem in fulfilling the basis requirement of patent law i.e novelty, non-obviousness and industrial application. Moreover, patent office might not be well-equipped enough to handle the patent claim. These problem are magnified for the developing and least developing countries which are obliged to confer IPR in new technology. The TRIPS agreement mandate for all the WTO countries to adopt and maintain minimum standard of intellectual property to allow patents in all field of technology. Patent activity are still to pick up at India patent office coupled with lack of Indian case law on patenting of nanotechnology.

The Indian Patent Act, 1970 and patent rules, 2003 regulate the grant, the operative period, the revocation and infringement of the patents. The patent act recognises the exclusive right

[58] WIPO, Exclusion from Patentable subject matter and exception and limitations to the right, standing committee on the law of patent , 13th session, SCP/13/3 (2008) 8-9

of a patentee to gain commercial advantage out of his advantage. But for patenting of nanotechnology the act does confer sufficient provision.

Challenges in Patenting of Nanotechnology

The patent Act of 1970 grants patent for an invention. But it is not mandatory for an inventor to apply for patent, he may chose to keep it secret. In the case of shinning Industries Vs. Shri Krishan Industries[59], the Allahabad high court held that an invention is not a property unless patented. It is due to this reason inventors apply for patent.

Basis Requirement

The term patent as per section 2(1)(m) means a patent for any invention granted under this act. As per section 2(1)(j) invention means a new product or process involving an inventive step and capable of industrial application. Before a patent is granted there are some per-requisites need to be fulfilled that are-

1. **New or Novel**

The concept of novelty in intellectual property jurisprudence lays down that only what is new at the time of filing of the application for a patent is patentable.[60] New invention means an invention which has not been anticipated by publication in any document or used in country or elsewhere in the world before the date of filling of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art.[61]

In the case of *Pope Appliance Corpn. Vs. Spanish River Pulp and Paper Mills Ltd*[62] the Privy Council stated Invention is finding out something which has not been found by other people. Further in the case of *Raj Parkash Vs. Mangat Ram Choudhary* it has been held invention as is well-known, is to find out something or discover something not found or discovered by anyone before...it is not necessary that the invention should be anything complicated. The essential thing is that the inventor was the first to adopt it. the principle,

[59] AIR 1975 All 231
[60] Verkey Elizabeth, Law of Patent, Second Edition, Eastern Book company
[61] Patent Act, 1970s, S.2(1)(l)
[62] AIR 1929 PC 38

therefore, is that every simple invention that is claimed, so long as it is something which is novel or new, it would be an invention....

The patent act 1970 requires an invention to be new in the sense that on the date of filing of patent application, it should not form part of the state of the art. State of the art' has not been defined under the Patents Act, State of the art comprises all the matter available to the public before the priority date of the invention by written or oral description, by use or in any other way. [63]', the following general principles are applied by the Patent Office to determine the novelty of an invention during the examination procedure by applying provisions of section 13, read with the provisions of sections 29 to 34 :

An invention is not considered to be novel-

(a) if it has been anticipated by publication before the date of filing of the application in any of the specifications filed in pursuance of application for patent in India on or after 1st January, 1912.

(b) if it has been anticipated by publication made before the date of filing or the date of priority of the application in any of the documents in any country; or

(c) if it has been claimed in any claim of any other complete specification filed in India, which was filed before the date of application though published after the date of that application.

In *Blakey and co Vs. Lathern and Co*[64], cotton LJ Stated that that to be new in the patent sense, the novelty must show the invention. In other words, in order to be patentable, the new subject matter must involve invention over what is old. *Lord Davery stated in Raickman Vs. Thierry*[65] that it was not enough that the purpose was new or that there was novelty in the application, so that the article produced was new in the sense, but there must be novelty in the mode of application.

But to prove this novelty under nanotechnology is not easy as what will constitute novelty under nanotechnology as will it be only on basis of size or an advance in the technology. In other words, if a existing technology in large size is reduced to the small size will it amount to novelty? As of now their is no clarity on this.

[63] Ahuja, V K, Law relating to intellectual property Rights, fifth reprint-2012, lexis-nexis Butterworths wadhwa.
[64] (1889) 6 RPC 184(CA)
[65] (1896) 14 RPC 105 (HL)

Inventive Step

It is part of the requirement of the novelty. Inventive step means a feature of an invention that involves technical advances as compared to the existing knowledge or having a economic significance or both and that makes the invention not obvious to a person skilled in the art.[66]

Non-obviousness

Patent law rewards the invention that are new, useful and non-obvious. Patent right are not available for new advances that are merely obvious extension or modification of prior designs that could be achieved without lure of patent rights.

A patent may not be obtained through a creation is not indistinguishably disclosed or described, if the difference between the claim sought to be patented and prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which they said subject-matter pertains.[67] In addition to other requirements, patentability depends upon the non-obvious nature of the subject-matter sought to be patented to person having ordinary skill in the art. A mere carrying forward of an original patented conception, involving change of form, proposition or degree or the substitution or equivalent is not an invention as will sustain a patent through the change may produce better results. The court invalidated the patent on a new fabric weave on the ground that it was like workman carrying forward old ideas.[68]

In the case of *Bishwanath Prasad Shayam Vs. Hindustan Metal Industies*[69] the supreme court observed that the expression does not involve any inventive step used in Sec 26(1)(e) of the Patenet and design Act, 1911 and equivalent word obvious had special significance in the terminology of patent law. The obviousness had to be strictly and objectively judged. Under Indian Patent law the requirement of the non-obviousness has been enumerated under section 2(ja) and section 64(f)[70]. The obviousness had to be strictly and objectively judges. For determining, several form of question have been suggested. One

[66] Patent act 1970, S. 2(1)(ja)
[67] Ibid 60
[68] Smith Vs. Nicholas, 22 L Ed 566: 88 US 112 (1874)
[69] (1979) 2 SCC 511, p519
[70] that the invention so far as claimed in any claim of the complete specification is obvious or does not involve any inventive step, having regard to what was publicly known or publicly used in India or what was published in India or elsewhere before the priority date of the claim

was suggested by *Salmond LJ in Rado Vs John Two & son Ltd* [71] was whether the alleged discovery lies so much out of the track of what was known before as not naturally to suggest itself to a person thinking on the subject, it must not be the obvious or natural suggestion of what was known previously.

Another test of whether a document was a publication, which would have a negative existence of novelty or inventive step was suggested as :-

Was it for practical purposes obvious to a skilled worker, in the field concerned, in the stae of knowledge existing at the date of the patent to be found in the literature then available to him, that he would or should make the invention the subject of the claim concerned.[72]

In *Graham V John Deere Co*[73], the US supreme court laid down certain factors to be considered to find out whether the invention was obvious or not. The court observed that to determine obviousness, court should consider-

1. The scope and content of prior art
2. The difference between the prior art and the claims at issue
3. The level of ordinary skill in the pertinent art.

In addition the court may use secondary consideration such as (a) commercial success (b) long felt unsolved needs and (c) the failure of others to solve the problem.[74]

In *Harwood V. Great Northern Rly Co*, [75] it was observed by the House of Lords that a mere application of old contrivance in the old way to an analogous subject, without any novelty or invention in the mode of applying such old contrivance to the new purpose, was not a valid subject matter of a patent.

As obviousness is a question of fact, it must be decided objectively. In deciding obviousness, all the relevant circumstances should be taken into account. The correct conclusion may well depend on the form and scope of the claim under consideration, constructed in the light of the relevant surrounding circumstance.[76] Obviousness id judged by viewing the invention as a whole against the state of art as a

[71] (1967) RPC 29
[72] Farbwerke Hoechst & B corpn. Vs. Unichem Laboratories AIR 1969 Bom 255
[73] 383 US 1 (1966) 1142
[74] Ibid 63
[75] (1864-65) 11 HLC 654
[76] L' Oreal's Application (1970) RPC 565, p 570

whole.[77] In Non-Drip vs Strangers[78] lord Romer stated that a combination should not be picked apart from its component.

Capable of Industrial Application

The invention for which patent is sought must have a industrial application. In other words it must be capable of being used in the industry.[79] No valid patent can be granted if the invention does not have application. Such utility or the industrial application should be mentioned clearly while filing the application for patent.

Disclosure

under patent act the inventor is granted exclusive right to exploit his invention for commercial gain, it imposes a duty of fully disclosing the invention in the complete specification so as to facilitate anyone from the public working the invention, once the period of protection expires. The full disclosure of the patented invention in mandatory. If inventor fails to disclose the invention fully, the patent will not be granted. The validity of such patent, even if granted, can be contrasted by an opposing party. The patent can be revoke on such contest succeeding.[80]

Other Issues

1. **Multi-Disciplinary Field**

Nanotechnology, is different from other discipline as it has a multi-disciplinary application, most of the invention under nanotechnology are applicable in different field like physics, chemistry, pharmaceutical, computer science and different field of engineering. Moreover, nanotechnology is developed at a nanoscale so it may touch upon all the industry which develop technology at nanoscale. Example- US patent No- 5, 874, 029 a nanopatent granted by USPTO for particle micronization and naniization by recrystallition from organic solution sprayed into a compressed anti-solvent. This invention has a usage in the field of food, chemistry, electronic, pharmaceutical, catalyst, polymer, pesticide etc. [81] This multi-

[77] Martin Vs Millwood, (1956) RPC 125, pp 133-34
[78] (1943) 60 RPC 135
[79] Patent Act, 1970, Sec2(1)(ac)
[80] Dr. B.L. Wadehra, Law relating to Intellectual Property, 5th Edition, universal law publishing co., new delhi
[81] Mark A. Lemly, Patenting Nanotechnology, Stanford Law School, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=741326, last accessed on 3-1-2015

disciplinary application of the nanotechnology poses challenge for both court and patent office. Moreover, a prior art search for patenting of a nanotechnology is not easy as it spread across many discipline.

A nanotechnology invention has an muti-disciplinary application. So, patentee may try to reap benefit by claiming the patent under different field. Some of the broad claim have been with respect with carbon nano-tube patent.

No fixed definition

Their is no fixed definition of nanotechnology available. It has been broadly been defined as the application of technology at a nano-scale. Thus, the size based definition of the nanotechnology creates problem for both inventor and patent office. Both inventor and patent officer has to be caution in searching for prior art in the area, as nano alone is not adequate search term**.** Failure to do so may lead to invalidation of the invention as patentable subject matter on the ground of anticipation of prior art. The lack of standardized terminology for NT leads to patent overlaps.

Disclosure

Nanotechnology invention is sub microscopic. Consequently, they are difficult to define in term of their application to traditional mechanical invention, material or composition. Clear term should be used to define the invention. The term nano particle or nano sized its self does not have a clear definition. But the specification should be defined in the clear term.

Indian Patent Act, 1970 and Nanotechnology

In India patent is granted under patent act, 1970. All the invention are protected under the patent act, 1970. The patent law recognises the exclusive right of a patentee to gain commercial advantages of his invention. This is to encourage the inventors to invesr their creative faculties, knowing that their invention would be protected by law and no one else would be able to copy their invention for certain period during which the respective investor would have exclusive rights. It is not mandatory for an inventor to apply for a patent for his invention. He may keep it as a secret. But the time it is disclosed to public he will not be able to claim the for infringement of his right.

All the invention made in different industries like biotechnology, nanotechnology etc are patentable under the patent act, 1970. Besides fulfilling the basis condition of novelty, non-obviousness, industrial application, disclosure it should be eligible for patent. Patent eligibility means the subject that is open to patenting. The Indian Patent act corresponds to the negative method of excluding the categories of invention that are not patent eligible. Patent law contains a non-exhaustive list of things which shall not be regarded as inventions. That list has been stated in section 3 of the act.

The challenges posed by section 3 to patenting of nanotechnology-:

Section 3(d): Discovery of a new property to a known substance

A prior identical product or process will anticipate even though it is contained in a different and non-analogous art from that of the latter invention. Anticipation is not avoided by the discovery of new use, property, or advantage of an old product or process. A patent cannot be valid unless it is new, inall its element as well as in the combination, if it is a combination.

The India Patent Act, 1970 was amended to comply with TRIPS requirement, in 2005 allowing new entities to be patented. The amendment prevented the ever greening of products. Nanotechnology, invention are small in size even if it of an existing technology. Or in other words, a existing technology in reduced in size., it will not be considered an invention unless it improve the efficacy of that product. So, a nanotechnology can be granted patent only when a new product is made which is an addition to already existing technology or knowledge in the field of nanotechnology. The conversion of an old contrivance to a new purpose was considered in Bilcare Ltd V. Amartara (P) Ltd., where the court found that there

must be difficulties to be overcome, requiring what is called invention, or there must be some ingenuity in the mode of making adoption;

The patentee found latent qualities in an old discovery and adapted to it a useful end. But that did not advance the frontiers of science in this narrow field so as to satisfy the exacting standard of our patent system. Where there has been use if an article or where the method of its manufacture is known, more than a new advantage of the product must be discovered in order to claim invention.[82]

Hence, to be patentable the invention under nanotechnology should be new in the sense that it should be addition to already existing knowledge. Mere reducing the size of a technology will not amount to the invention, even if it is considered as invention it will not be patentable unless it enhances the efficiency of the product.

[82] General Electric Co. Vs Jewel Incandesecent Lamp Co., 90 L Ed 23

Conclusion

With innovation driving the industry in the market. Every company in the world is trying to innovate something. The company indulge in the nanotechnology are trying hard to innovate. As it is the emerging industry and will take over the market in the future. Reduction in the size of TV is one of the example of nanotechnology another example of it can be reduction in the size of the computer, now it is available in the size of a pam from size of room. Nanotechnology, is slowly becoming the driving force of an company. Every company indulge in nanotechnology is trying to protect it under intellectual property rights. Under intellectual property right all the creativity are protected and innovation are also protected under Patent. Patent means a monopoly right granted to a person to exploit his invention for a limited period of time. During the period, the inventor is entitled to exclude anyone else from commercially exploiting his invention. The grant of patent not only recognises and rewards the creativity of the inventor, but also acts as an inspiration or catalyst for further inventions. But before a patent is granted, the inventor has to fulfil some of the pre requisites, such as novelty, non-obviousness, industrial application, patentable subject matter, full disclosure. but under nanotechnology to fulfil such requisites is not easy.

Nanotechnology is science, engineering at a nanoscale. Apart from full disclosure of the invention the inventor has to surpass the requirement under the act. Under nanotechnology to fulfil the novelty requisites is not easy as only reducing the size of an existing technology does or does not amount to novelty, the Supreme of India has not cleared the stand on it but in US it does not amount to novelty. Further, the novelty should be such that it should be addition to the prior art i.e. it should be addition to the already existing knowledge on the subject matter. Thus, merely reducing the size of technology will not amount to the novelty as the technology already exists only the size has been reduced. Further, it should be non-obvious for the person skill in the art i.e. for the person skilled in the subject-matter of patent application. But under nanotechnology it might be obvious for the person who is engineer in the field of nanotechnology. Further more, the invention should be patentable subject matter, in other words it should not be under exception to patentable subject matter. Under India Patent act, 1970, section 3 states the invention which are not patentable. As per section 3(d), the mere discovery of a new form of known substance which does not result in the enhancement of the known efficacy of that substance or mere discovery of any new property or new use for a known substance or of the mere use of known process, machine or apparatus

unless such known process result in a new product or employ at least one new reactant.[83]this clause further create a hindrance for patenting of the nanotechnology. Adding to the woes their is no fixed definition of nanotechnology, which create a problem for identification as to whether the technology is to be considered as nanotechnology or not. Further, being a multi-disciplinary field create a problem for a prior art search as it may be novel in one field but might be obvious in another field. Thus, it is not easy to get a patent under nanotechnology.

For patenting of nanotechnology a separate section of patent should be created under which only application relating to the nanotechnology are considered. In US nanotechnology patent are considered under separate class of patent. Thus, making is easy to claim patent in the field of nanotechnology. Further, if a separate class is created it will easy to undertake prior art search. As the a separate data bass will be created for the innovation under nanotechnology. Moreover, patenting of nanotechnology should be allowed for limited number of field as being a multidisciplinary field a innovation might be patentable under different claims. But it should be restricted to 3 claims and innovator should make primary claim as to the field in which it is surely patentable and a fixed definition of nanotechnology should be made, as to clarify the technology to be part of nanotechnology or not.

In India, to create a separate class of patent for a technology would be not easy. Further, there is need for amendment to the section 3(d) of the patent act, 1970 as it is creating hindrance for the patenting of the new innovation. Hence, to promote new technology and boost economy there is need for a change in conventional law working in the world. So, as to make it more feasible with the changing technology.

[83] Dr. B.L. Wadehra, Law Relating to Intellectual Property, 5th Edition, Universal Law publishing Co.

Chapter 4: Hurdles in Patenting of Biotechnology

Introduction

Biotechnology has been developing at dramatic speed. It is omnipresent and is indulge in manufacturing of food, pharmaceuticals, fertilizers, protection of environment etc. Biotechnology is a modern science revolutionizing production in different industries. Biotechnology mainly comprises of chemical or pharmaceutical or invention relating to plant and animal(agriculture).[84]

Biotechnology is not new to the world but has been in existence for years. first stage of its evolution can be traced to the traditional knowledge like preparing fermented food like cheese by employing living micro-organisms like fungi, bacteria etc. secondly, it can be traced to the Pasteur era which involved the production of alcohol, fermentation of antibiotic, development of classical vaccine like cholera, typhoid, yellow fever etc. thirdly, which begin from 1970 involved recombinant DNA and hybridoma technology. Fourth, generation would see a combination of biotechnology and information technology.[85] The term biotechnology does not have a specific definition, but has been defined by different author differently. The word biotechnology was coined by Karl Earky, who defined term in such a manner that the technologies which include all such works by which products are produced by the aid of raw material such as living organism.[86] With time it has been defined in such a manner that now it has acquired a confusing interpretation.

As per black law dictionary Biotechnology is a branch of molecular biology dealing with the use of biological process to produce useful medical and industrial materials. According to the organisation for economic corporation and development biotechnology includes any technique that uses living organism or part of organism to make or modify product to improve plants or animal or to develop microorganism for specific use.[87] Biotechnology is the synergy of biological science and technology. It can be defined as the controlled and deliberate manipulation of biological systems (whether living cells or cell components) for the efficient manufacture or processing of useful products.[88] Biotechnology is concerned with

[84] Sujith Bathacharya, patenting in biotechnology, Desicoc bulletin of information technology, vol 27 No 6
[85] Archana K, Do we need patent protection to biotechnology invention, International journal of Scientific and Research publications, Vol 3, Issue 4, April 2013, I
[86] Supra 85
[87] Patent and Innovation: Trends and Policy challenges. OECD, Paris, 2004
[88] what is biotechnology? http://www.dcu.ie/biotechnology/about.shtml

the use of living organism or biological system in the manufacture of drug or any other product. Biotechnology is generally concerned with the

Change in genetic make-up of an organism called as genetic- engineering. Two sector to which biotechnology has made significant contribution are pharmaceutical and agriculture. Brodly, biotechnology can be classified : industrial biotechnology and agricultural biotechnology. Industrial biotechnology refers to chemical and pharmaceutical substance derived from or process pertains to the plant and animal kingdom. Agricultural biotechnology involves use of genetic engineering to develop new plants and animal.[89] This technology has been dominated in developed country as compared to developing countries. Developing countries have long posed capabilities for plant breeding, through public sector research institutions, for which biotechnology provides new tools.[90] Like other invention in other industry invention under the biotechnology are seek to be protected under patent law of a country. Biotechnology invention or subject-matter of patenting can be classified as-

1. Invention relating to living organism or materials such as living entities' of natural or artificial origin (plant, animal) or product of biotechnology
2. Invention relating to process of creation of such products or method/ process of making bio-matter or product
3. Invention relating to usage of biological materials or this organism or use of such bio material.

All such invention are product of human intellectual and application of biological process. These efforts deserve protection to reap the fruit of invention of biotechnology. Patent protection for such invention is of immense commercial importance. But before such invention are granted patent their are many hurdles beside the requirement of the patent law. Invention under biotechnology has raised peculiar challenge to ethics; morality and access to these technologies tend to cloud the debate in developing countries. These challenges are complicated by the rapid advancement made in science and technology which often require the criteria for patentability of biotechnological invention redefined.

[89] Feroz Ali Khader, The law of patents, with special focus on pharmaceuticals in India, , Lexix Nexis, Butterworths, 1st edition

[90] Jaiashree, Watal, Intellectual property Rights, In the WTO and developing countries, f, Oxford India paperback

Challenges in patenting of biotechnology

Moral and ethical Issue

Biotechnology involve patenting of life forms. In other words, under biotechnology a claim for patent is filed seeking protection for material which are living in nature already existence in nature. Such grant of patent to life form like cells, gene, mice has invoked moral and ethical debate all over the world. However, what are moral and ethical changes with time. The main argument surrounding the issue is that patenting of human gene may block research, innovation and create obstacle for life saving treatment.[91] Further, "Human DNA bears image of god" and to own them and temper with it might hurt sentiment of many. Plant, animal and microorganism are part of nature, hence any manipulation with their molecules or conversion of species or any part of them, is not patentable as it might be counter to the interest of the country. Further, people are of the opinion that a gene should not be made property of anyone. Moreover, before granting a patent invention should be subjected ethical cum moral scrutiny, in order to maintain moral standard of the society. Moreover, TRIPS permits WTO member to exclude immoral invention from patenting. Article 27.2 provide such right. Apart from this article 27.3(b) provide allow WTO member to exclude subject matter form patenting.

A patent provide a monopoly right to the patentee, it does not grant a possessory right to the patentee instead exclude other from exploiting the invention. example, a patent granted for human cell does not make the patentee the owner of the cell, but it provide exclusive right to the patentee to exclude other from using the DNA sequence and information derived from it.[92] moreover, the term like moral or ethical has not been defined anywhere. These are subjective term. Moreover, patent forum are not the ideal forum to deliberate issue of morality and ethics.

In India, section 3(b) provide ground for rejection of patent application on the ground of morality. Whereas in US only human body are excluded from patenting on the ground of morality.

[91] Immoral Inventions, (2010) 22 SACLJ931
[92] Supara 91

Innovation Vs Discovery

Genetic manipulation has raised serious concern as to whether it is a discovery or an invention. As it is naturally found in nature. Further, all the matters connected with life are presumed to property of God.[93] The genetic resources are not granted patent so easily.

Patent is granted for invention not for discovery. The difference between the two is an invention is creation of something new which has not been existence before whereas the discovery is identification of thing which has already been in existence but has come to knowledge of human now. In simple word, discovery relates to new information and knowledge which already exist in nature. Whereas Invention relates to creation of new product or process which never existed before.[94]

It does not involve creation of new thing. Under biotechnology the raw material used is naturally occurring, in other words, is already in existence and the manipulation of same amounts to invention. In other words, the discovery are not patentable but a human intervention to already existence natural resource amount to invention. human intervention make it new, natural, man-made hence patentable. In relation to biotechnology human intervention make an discovery an invention. Therefore, till the addition of human ingenuity a biological product remains an discovery and the application of human ingenuity makes it an invention.

But the issue remain at what stage discovery ends and innovation begins. This issue has been settled by the court in the case of Dinninaco AG v. Controller of Patents[95] court ruled that the patent was for laboratory preparation(a process) of bursitis vaccine. A biological entity may be patentable if the technical intervention of man had resulted in an artificial state of affairs which does not occur in nature. The isolation and cultivation of naturally occurring micro-organism which have some new use satisfy the requirement of technical intervention.

In simple words, it can be stated that the product of nature become product of man on account of intervention of human ingenuity. This intervention give rise to new product having some new feature which were not present in it

[93] N R Subbaram, Patent Law Practices and Procedure, 2nd edition, wadhwa Nagpur,
[94] P. Narayanan, Intellectual Property Law, 3rd edition, Eastern Law house, pp 19
[95] 1 PLR 2002 july 255

earlier, which make the subject-matter patentable. moreover, isolating of product from its natural existence is considered as invention under the patent law.

Basis requirement of patenting

1. Novelty

The fundamental principle of patent law is that patent is granted for invention which are novel and have utility. No fixed condition can be laid what constitute a new invention. an invention is considered to be new if it has not been anticipated by prior art, prior art means the compilation of all the knowledge on the claimed matter existing prior to the filling of patent application. The knowledge of an invention to be considered as relevant prior art should satisfy any one or the following-:[96]

a. By the description of the invention in a published writing or document
b. By description of invention in spoken words uttered in public
c. By use of the invention in public or by putting the public in a position where any member of the public may have access to it.

In simple words, novelty of invention is determined considering the knowledge available anywhere in the world relevant in the field at the time of filing the application for patent. In other words, an invention cannot be patented if invention is already known in any part of world on day of filing the application for patent.

In US patent is granted to the first to invent not to file. The first requirement is the applicant must himself have invented the subject-matter of the invention. the invention is not considered novel

1. Invented by someone else[97]
2. Known or used by other USA or patented or described in printed publication anywhere in the world [98]the word printed is applied even to the documents in electronic form[99]

[96] Rama Sarma, Commentary on intellectual property laws, edition 2007 vol 1, wadhwa Nagpur.
[97] 35 USC 102(g)
[98] 35 USC 102(a)

3. Described in a US patent application that is subsequently granted[100]

In US requirement of novelty of gene is based on whether DNA sequence of gene sought for protection is available in prior art and even a slight difference in sequence can avoid anticipation.[101]

In India, can be patented in most of patent office if they are purified and isolated from the form in which they occur in nature. The applicant must be able to prove, existence of gene was not known and he was first to isolate and define its utility.[102]

Non-obviousness (Inventive step)

The term obvious has not been defined under the patent act, the question considered to determine requirement of inventive step is "whether or not an invention would have been obvious to person ordinarily skilled in the art".[103] It can be stated to be a circumstance where a person of skill in the field, on going through the specification would complete the product. Therefore, even if any of two ingredients i.e. technical advances or economic significance or both are available, if such invention enables a person skill in the field on going through the specification would complete the product, such invention can never be treated as inventive step and consequently no patent can be validly issued.[104]

In considering the obviousness, court must make factual enquiries as to-

1. The scope and content of the prior art
2. The difference between priort art and the claims at issue
3. The level of ordinary skill in the pertinent art

Under biotechnology the process may be obvious as to isolating DNA sequence but product might be unique.

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[99] Philip W. Grubb, Peter R. Thomsen, Patents for chemical, pharmaceutical and biotechnology, 5th edition, oxford

[100] 35 USC 102(e)

[101] Samatha A. Johnson, A comparison of patentability and patent scope of biotechnology invention in United states and European union, 35 AIPLA Q.J. 193 , 215(2007)

[102] Malathi Lakshmikumaran,Patenting of Gentic Invention, Journal on Intellectual Property rights, Vol 12, Pg. 45-56, January,2007

[103] Ibid 93

[104] V.K. Ahuja , Law Relating To Intellectual Property Rights, 1st edition, Lexis Nexis Butterworth

Patentable subject matter

Patentable subject matter are defined as any new and useful process, machine, manufacture or composition of matter or any new and useful improvement thereof. Naturally occurring compounds are considered patentable if they are isolated from their natural environment and found to be useful.[105] Under section 35 U.S.C 101 it is now well settled living matter are patentable as long as they are product of human ingenuity. The living matter may be virus, cell, single-cell or multi-cellular organism.[106]

Section 3 of the Patent act, 1970 stated the invention which are not patentable. it exclude many invention related to bio-technology inventions such as Invention against natural laws, Invention contrary to public order or morality, Discovery of a living thing occurring in the nature, Method for treatment of animal or human being etc.

US has wider application then the Indian law.

Utility

Last requirement of the patentability is the invention should have an industrial application. In U.S. the utility requirement has been set forth in 35 U.S.C 101. For determining the utility of biotechnology invention Federal court has laid down that the gene sequence which has specific and substantial utility will be granted patent protection.[107]

The patent protection is not available to invention which are abstract in nature, it need to have an industrial application. The use may not be for profit but may also include for agriculture use also.

Microbiological inventions

Micro biological invention involve use of a new strain microorganism to produce a new compound or to produce a known compound more efficiently (for example higher purity or yield). The new organism may have been found in nature or may have been produced artificially induced random mutation or by genetic engineering.[108] The term microorganism not only include bacteria and fungi but also virus and animal and plant cell. In US, USPTO

[105] Ibid 99
[106] Rameshwar, Patenting in biotechnology- An overview.
[107] In Re Fisher
[108] Ibid 95

does not grant patent to living system easily. In 1980, however SC in the case of *Diamond vs Chakrabarty*[109] held that the new strain of bacteria produced artificially was patentable.

Further, the discloser is another challenge for patenting of invention of micro-organism,. As it is practical impossible to define a strain of microorganism unambiguously by written description. The approach that has been developed to counter the challenge is that of deposition of the strain in recognized culture collection, which will maintain the strain in a viable condition and make sample available to the public. In the case of In re *Argedoulis*[110] held that such deposit is sufficient to meet the disclosure requirement of the US patent law.

Indian scenario

The TRIPS agreement makes it obligatory for member states to protect bio-technology invention but allow to exclude plant and animals from patentability. It is obligatory for them to protect micro-organism and biological process for the production of plant and animal. In India after 2002 amendment to Patent act, microorganism was made patentable. this provision has been incorporated under section 3(j) of the patent act.

The patenting of micro-organism was considered in the case of *Dimminaco AG v Controller of Patents and Designs*, a case which involved an invention relating to a process for preparation of infectious Bursitis vaccine for protecting poultry. The Assistant Controller of Patents and Designs rejected the application on the ground that it did not constitute an invention under S 2(1)(j) of the Patents Act, holding that the process of preparing the vaccine which contains a living virus cannot be considered as ‘manufacture' under the old definition of invention. The Assistant Controller further held that the vaccine with living organisms cannot be considered a substance. An inanimate object can be described as a thing or item but not as a living one. Microorganisms cannot be considered an inanimate substance as it cannot be converted physically or chemically to any other product. On an appeal preferred under S 116 of the Patents Act to the Calcutta High Court, the court took into account the practice of the Patent Office in granting patents for end products containing living virus and quashed the order of the Controller and directed the reconsideration of the patent application.

[109] 206 USPQ 193
[110] 168 USPQ 99

The case was decided under the provisions of the Patents Act before the Patents (Amendment) Act 2002 came into force. The said Amendment introduces S 3(j) which allows patents for microorganisms. The decision in the Dimminaco case considers the practice of the Patent Office in granting patents for end products containing living virus and arrives at its conclusion to allow patents for microorganisms on the basis of such practice.

Transgenic Plant

The transformation of plant cell poses challenges which are not found for animal cell. But, now technique have developed which allow transformation: some on verge of bizarre such as biolistic transformation, in which DNA molecules are placed on the surface of micronized glass beads that are then physically shot into plant cell.

Once transformation occur, conventional breading technique enable production of plants the seeds of which pass the desired phenotype to further generations.[111]

The aim of such transformation is that it would not only enable transformation of desired characteristic but will provide extra advantages such as high yield, growth in arid condition, additional nutritional quality and others.

Patenting of such transgenic plant can be sought in US. In the case of "Hibberd[112]",board of appeal ruled that utility patent can be granted to plant under PPA and PVPA. Further, boards of appeal ruled that congress enacted plant-specific act out of concern that plant would not qualify for patent protection and not because the Congrees thought plants were inherently un patentable. Thus, board of appeal concluded that genetically engineered plants, seeds and plant tissue are patentable.

In US two act specifically deal with plant variety, U.S. plant patent act, 1930, this act provide patent protection to the developer of new variety of many asexually propagated plants. Further, U.S. Plant Variety Protection Act, 1970 provide patent rights for developer of new varieity of seed- propagated plants

India, has adopted sui-generis system for protection of plant variety and farmers right act, 2001. It provide for the establishment of an effective system for protection of plant varieties, the right of farmers and plant breeder. Variety has been defined under the act as variety

[111] Ibid 100
[112] Ex parte Hibberd, United States Patent Quartely, 1985 443

means a plant grouping except micro-organism within botanical taxon of lowest known rank, which can be:

1. Defined by the expression of the characteristic resulting from a given genotype of that plant grouping
2. Distinguished from any other plant grouping by expression of at least one said characteristic
3. Considered as a unit with regard to its suitability for being propagated which remain unchanged after such propagation and include propagating material such as variety, extant variety, transgenic variety, famers variety and essentially derived variety.[113]

Hence, the transgenic plant are granted protection both in U.S. and India.

Patenting of Animal, plants and human cells

In U.S. first patent on multicellular organism was granted in 1987, further in 1988 a US patent was issued on the Harvard Onco Mouse. On account of which there was huge cry for granting and US politician called for a law imposing a moratorium upon animal patenting but no such law was passed. Subsequently, it has been made clear that any life form is patentable provided that human technical intervention is required in its production.

In India section 3(j) prohibits granting of patent protection, as per provision no patent can be granted for plants and animal, parts of plant or the animal and for essentially biological process for the production or propagation of animals or plant.

Transgenic Animal

With the advancement of technology it is possible to use various techniques, to introduce extraneous genetic material into a fertilized mammalian ovum, insert the ovum into a pseudopregant female and obtain offspring in which the genetic material has become

[113] V K Ahuja, Law relating to Intellectual Property Rights, First Edition, lexis nexis Butterworths Wadhwa Nagpur, pp 514

incorporated into the genome. Such transgenic animal has two main uses at present: one is as animal produced can be used for research purposes, another is source of useful materials. [114]

In US transgenic animal is granted protection, in US anything under the sun made by man is patentable".[115]

Where as in India no patent protection is granted to transgenic animal, it is prohibited under section 3(b) of the patent act, 1970.

Recombinant DNA

Genetic information is carried in the cell by molecules of DNA. Many of the DNA sequence which have been patented for year are human genes, because they are code for human protein. Emphasis has always been on upon the protein, with the DNA or the gene seen simply as a means for the production of the product of interest. Such identification of gene is significant, many companies and universities are engaged in research to identify gene which are associated with specific disease. Finding such disease related gene often result from a combination of biotechnology with classical genetics. A different way of looking for human genes is that of sequencing all or part of the entire human genome, finding which sequence corresponds to expressed genes, correlating gene expression with cell type and disease state.[116]

Patenting of such genetic resources has been existence of US since 1998, when USPTO took position that purified and isolated DNA composition comprising would normally meet the requirement for enablement and written description. In 2002, the USPTO introduced new guideline providing that DNA sequence must have a stated utility that was substantial, specific and credible in order to be patentable.[117]

In India, genetic resources are patentable provided it satisfy the requirement under the act.

[114] Ibid 92
[115] Diamond vs Chakarborty 447US 303 (1980)
[116] Ibid 99
[117] Supara 99

Pharmaceutical Industries

Pharmaceutical industry has been growing at a very fast pace, because of the importance of public health and the unrelenting need for drugs to alleviate human suffering.[118] Like any other industry involving intellectual labour, IPR play a significant role. Patent play a vital role in the pharmaceutical industry. Industry try to develop new product or process, such product are mainly develop a new use of a known substance and seeking a patent for such a product become a challenge for pharmaceutical industry. Although, new medicine develop are patentable provided the essentials under the statue of a country are fulfilled. The problem is for patenting for new use of known substance as it may be not considered as novel.

Generic Drugs

Generic Drug are marketed under a non-proprietry or approved name rather than under a brand name. They are frequently as effective as and cheaper than a brand name drugs. Because of this low price generic medicine is the only medicine which poor can access. A generic drug is a drug which is produced and distributed without a patent protection. It may have a patent on formulation but not on active ingredient. According to U.S. Food and Drug Administration, generic drug are identical or within an acceptable bioequivalent range to the brand name counterpart with respect to pharmacokinetic and pharmacodynamic properties.

Novartis Case

Facts- in 1997, Novartis AG, a pharmaceutical company based in Switzerland, filed a patent application at paptent controller office, Madras for beta-crystalline of imatinib mesylate, brance name Glivec(gleevec) on the ground that it invented the beta crystalline salt from imatinib mesylate of the free base, imatinib mesylate of the free base, imatinib.

Novartis's patent application was filed in mail-box and was not opened until 2005 as the TRIPS agreement permitted developing countries auch as India to revamp their system according to obligation under the TRIPS. For meanwhile, Novartis was granted Exclusive Marketing Right for marketing Gleevec. On basis of EMR it obtained injunction order preventing some of generic manufacture from manufacturing and selling generic version of the medicine.

[118] Feroz Ali Khader, The Law of Patents- with special focus on pharmaceutical in India,

In 2005, India amended its patent law to comply with obligation under TRIPS and added section 3(d) of the Patent act to prevent ever-greening.

After 2005, CPAA and other generic companies filed pre-grant opposition against Novartis patent application for imatinib mesylate, claiming, inter alia, tht Novartis alleged invention lacked novelty was obvious to person skilled in the art and it was merely new form of a known substance that did not enhanced the efficacy and was not patentabe as per section 3(d). It was based on the fact that Novartis had already been granted a patent in 1993 in U>S. And other Jusidication for active molecule, imtinib and that present application only concered a specific Crytalline form of salt from that compound.

In year 2005 the patent application was rejected on the ground of section 3(d). The application was rejected by Madras High Court as well. Then the matter was taken up by the SC-

The court first analysed question of prior art by looking into zimmerma patent and related academic publications. It was clear from the Zimmerman patent that imatinib mesylate was not new and does not qualify the test of invention as laid down under section 2(1) (j) of the patent act, 1970.[119] Futher court, ruled that beta crystalline from of imatinib mesylate being a pharmaceutical substance and moreover a polymorph of Imatinib Mesylate, it directly run into section 3(d) of the act with the explanation appended to the provision.

While applying section 3(d) of the act, the court decided to interpret efficacy as therapeutic efficacy because the subject matter of the patent is a compound of medical value. Court acknowledged that physical efficacy of imatinib mesylate in beta crystalline form is enhanced in comparision to other form and that the beta crystalline form of imatinib mesylate has 30% increased bio-availability as compared to imatinib in free base form.[120]

The court upheld the view that under Indian Patent Act, for grant of pharmaceutical patents apart from proving the traditional test of novelty, inventive step and application, there is new test of enhanced therapeutic efficacy for claims that cover incremental changes to existing drugs.[121]

[119] Novartis Vs Union of India, Para 157
[120] Ibid 119, para 187
[121] Rajeev Dhavan, Novartis and Health- An analysis, 11th April

In India, patenting of such product is prohibited under sec 3(d) of the act. Section 3(d) serves two function first it is designed to discourage patent ever greening by prohibiting grant of patent on derivative form of known substance unless derivative form has significantly enhanced efficacy.[122] The term efficiency has not been defined under the act. moreover, whether a product efficiency has been enhanced depends upon the discretion of the patent office.

Further more, court pointed out that subject patent application was filed during a time of transition in Indian patent law, especially with regard to striking section 5 which had barred product patent and adding section 3(d), for which there was no case law yet. The court also stated that the decision was intended to be narrow " We have held that subject product, the beta crystalline form of Imatinib Mesylates does not qualify for the test of section 3(d), which bars the ever-greening. It will grave mistake to read this judgement to mean that section 3(d) was amended with intent to undo the fundamental change brought in the patent regime by deletion if section 5 from the patent act. that is not said in judgement.[123]

Analysis of the Judgement

The judgement is a landmark judgement in the field of patent law as it is one of its kind, the SC has not decided such cases in past. From the judgement is can be concluded that Indian Patent law is rigid and narrow then the US law, as under US law Novatris would has been granted patent as the US law consider improvement to existing substance as invention.

Further the ruling applies that section 3(d) of the act prevent patenting of new form of an existing compound. The court however, clarified that this provision does not bar patent protection to incremental invention of chemical and pharmaceutical substances.

Court stated that even if pharmaceutical substance meets requirement under the Patent act, it still need to satisfy the condition of demonstrating better therapeutic efficacy.

Section 3(d) is born of contention for the pharmaceutical industry. Firstly, because it bars the patent on the ground of improvement in the existing substance which as compared to US is rigid law secondly, due to its vagueness. Though, the tem efficacy has been interpretated by the court . but what constitute that is still not clear. But the ruling will not affect the patent

[122] Ahibhusan De & Uma Baskaran, What the New Patent Regime Means In Practice, MANAGING INTELL. PROP., Jul./Aug. 2005, at 63-64
[123] Para 191

for drugs that meet the requirement laid down under the patent law, but can prevent foreign firm from launching new drug i India, limiting revenue growth opportunity for listed Indian subsidiaries.

This ruling will help several life saving medicine as generic drug, buy at cheaper rate. As the SC has held that modification of well known cancer-fighting drug is not patentable new invention.

The judgement allows suppliers to continue making generic copies of Swiss firm Novartis Glived or Gleevec. Observer says that court judgement set a precedent against practice of ever-greening- a strategy through which drug manufacture introduce modification of drug to extend the five year patent on them. They say that other evergreen patent pallication could be rejected citing this judgement, helping to keep many life saving drug out of the patent regime and pushing down the cost.[124]

[124] The Hindu, " Landmark Verdict give Big boost to Cancer Patients, 2nd april 2013, last accessed on 3-4-2015

Intentional Framework on Biotechnology

WIPO on Biotechnology.

The criteria prescribed for patenting is applicable for all the technical invention, but the application particulars for biotechnology invention are different from other type of application.

While in principle, in accordance with the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), patents shall be available for any inventions in all fields of technology, the issue of patentability of biological materials isolated or derived from naturally occurring living organisms has triggered widespread discussions. Some argue that such biological materials are mere "discoveries", and therefore not patentable, while some others argue that they are man made "inventions".

With respect to industrial applicability (usefulness) and sufficiency of disclosure, the exclusive patent rights may be granted only where an appropriate level of concrete and practical use of the biotechnological invention is disclosed in the patent application.

In addition, a number of typical issues relating to biotechnological inventions result from the fact that biological material is capable of reproducing itself. This specific characteristic requires determination of law as to the scope of legal protection of future generations, exhaustion regimes, special rules, if any, for plant and animal breeders or farmers, etc. Further, the development of genetic engineering resulted in the possibility of overlap between plant variety and patent protection even in countries where patent protection for plant varieties is excluded. While each of these systems provides a scope of protection and rights as well as limitations that are distinct from each other, the interplay between the two systems is at scrutiny.[125]

Hence, as per wipo the only challenge which is hinderance in protecting the biotechnology is the requirement to fulfil the basic condition i.e. novelty, disclosure, industrial application. If all this condition are fulfilled then a patent for biotechnology can be grated.

[125] Biotechnology ,http://www.wipo.int/patents/en/topics/biotechnology.html,

Budapest treaty on the international recognition of the deposit of microorganism for the purpose of patent procedure, 1977

Where an invention involves a microorganism or the use of a microorganism disclosure of the on invention for the purpose of grant of patent is not possible in writing but can only be effected by deposit of a sample of microorganism with a specialized institution. The deposit of micro-organism, which also includes biological material, is necessary for the purpose of disclosure particularly for invention relating to food and pharmaceutical fields. The main feature of the Treaty is that a contracting State which allows or requires the deposit of microorganisms for the purposes of patent procedure must recognize, for such purposes, the deposit of a microorganism with any "international depositary authority", irrespective of whether such authority is on or outside the territory of the said State.[126]

Nagoya protocol on access to genetic resources and equitable sharing of benefits, 2010

The objective of this protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including appropriate access to genetic resource and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and sustainable use of its components.[127]

The Nagoya Protocol applies to genetic resources that are covered by the CBD, and to the benefits arising from their utilization. The Nagoya Protocol also covers traditional knowledge (TK) associated with genetic resources that are covered by the CBD and the benefits arising from its utilization.[128]

Article 5 of the protocol provides for benefit sharing arising from the use of genetic resources as well as subsequent application and commercialisation. The sharing must be fair and equitable. Parties are at liberty to determine what constitute such sharing according to thei

[126] http://www.wipo.int/treaties/en/registration/budapest/summary_budapest.html, Summary of BudapestTreaty last accessed on 2-4-2015
[127] Nagoya Protocol
[128] http://www.cbd.int/abs/about/ , about Nagoya protocol. last accessed on 3-4-2015

needs through mutually agreed terms. Countries may stipulate minimum terms that ought to be included to fulfil the fair and equitable criteria in their nation law. Specific obligation to support compliance with domestic legislation or regulatory requirement of the party providing genetic resources and contractual obligations reflected in mutually agreed terms are significant innovation of the protocol. these compliance provisions as well as provisions establishing more predictable condition for access to genetic resources will contribute to ensuring the sharing benefits when genetic resources leaves the party providing genetic resources.

In other words the protocol provide for sharing of benefits with the local community, arising out of the use of natural resources. By promoting the use of genetic resources and associated traditional knowledge and by strengthen the opportunities for fair and equitable sharing of benefits from their use, the protocol creates incentives to conserve biological diversity, sustainably use its components and further enhance the contribution of biological diversity to sustainable development and human well-being.

Conclusion/ Recommendation

Biotechnology and pharmaceutical industry are one of the growing industry all over the world. Both the industry involve plays a significant role in a country, for protecting the health of the public. A lot of investment, time, efforts and intellectual labour is spend for the development of the new product. Under biotechnology the innovation mainly involve the life forms, patenting of which always has been a controversial issue all the world. But there are various challenges which need to fulfilled before the granting of patent to any invention in biotechnology or genetic resources. The never ending debate of discovery and invention is the main hindrance before granting patent to any genetic resources. Moreover, the ethical, morality issue involved. Many countries like Europe, UK, India has inserted a clause under their respective act to deny patent on this ground.

The biotechnology invention has further to satisfy the basic requirement of novelty, disclosure, non-obvious and utility which are difficult to prove in any genetic or biotechnology invention. The essentials for patenting a product or process i.e. novelty, non-obviousness, industrial application and disclosure are completely fulfilled under biotechnology. Moreover, the genetic resources used for the production of any product under biotechnology are patentable not in their natural form only if their is an human intervention as such intervention makes the naturally occurring material, manmade material. This only differentiates between the discovery and invention which has become a debatable issue for patenting of genetic resources.

The law for biotechnology is rigid in India as compared to that of the US. US has the highest number of patent, and the system for granting the patent is relaxed as compared to the India. as the law for the patent is easy in US and the law is industry friendly there, which motivates the companies to invest their time efforts and money to develop new technique and method under biotechnology.

There is need for amending the Indian patent law, to make it more industry friendly and encourage investment in the industry. Relaxing the system will not only help grow the company but will also help to grow the economy. Its time for india to adopt some of the practices of US.

For pharmaceutical industry as well, India need to amend its law. Especially the section 3(d) of the act as it is the main hindrance for an pharmecutical industry. Novatis case , is the

biggest example of such hindrance. Moreover, other provision like that of bolar provision under section 107(a) and that of compulsory licensing should be amended so as to make the law industry friendly and encourage the company to invest in India.

Chapter 5:- International Framework and Intellectual Property Rights

Since the emergence of modern protection of intellectual property during industrialisation in 19th century, the process is governed by some international framework, which lay down the minimum standard for the protection of the IPR and for promotion and protection of IPR. Bilateral in beginning, seeking to secure comparable level in neighbouring countries in the effort to combat counterfeiting and wide spread copying, intellectual property agreement amount to the first multilateral instrument in international economic law, before the GATT was founded after WWII.[129]

Paris and Berne convention of 1883 and 1886, respectively, multilateral zed great number of bilateral agreement and attempted to bring harmonization in key area relevant to international commerce. While these treaties were amended and many additional treaties were implemented related to IPR under the United Nations, world Intellectual Property Organisation but the developing countries refused to accept advance standard of protection commensurate with the domestic law. This changed, during the geopolitical changes of 1989, during the GATT , developing countries agreed to global minimal standard in the agreement on Trade-Related Aspects of Intellectual Property Rights(TRIPS) , which come into force in 1995.

TRIPS agreement

WTO is an international organisation which regulates trade between the counties. WTO an international body developed through series of negotiation. Has played an integral part in increasing the trade between the country. At present, 148 country are member of the WTO. Every member to the WTO has to adhere to the 18 specific agreement annexed to the agreement establishing WTO country has to comply with every agreement , they don't have option. The TRIPS agreement of WTO is of paramount importance both in term of substantive and procedural law. It expounded basic rules in all the field of intellectual property protection ranging from copyright and related right, trademark and geographical indications, industrial design, layout deign of integrated cicuit and novel protection of undisclosed information.

[129] Concise International and European IP law, TRIPS, Paris Convention, European Enforcement and Transfer of technology, second edition, Wolter Kluwer

The TRIPS Agreement introduced global minimum standards for protecting and enforcing nearly all forms of intellectual property rights (IPR), including those for patents. International conventions prior to TRIPS did not specify minimum standards for patents. At the time that negotiations began, over 40 countries in the world did not grant patent protection for pharmaceutical products. The TRIPS Agreement now requires all WTO members, with few exceptions, to adapt their laws to the minimum standards of IPR protection. In addition, the TRIPS Agreement also introduced detailed obligations for the enforcement of intellectual property rights. The agreement offers rule on procedural rights and obligation for both civil and administrative procedure and set minimum standard for protection through penal law. It addresses standards on registration of rights.

Moreover, the agreement seeks to strike a proper balance between appropriation and competition and to take into account need to protect public good and welfare.

However, TRIPS also contains provisions that allow a degree of flexibility and sufficient room for countries to accommodate their own patent and intellectual property systems and developmental needs. This means countries have a certain amount of freedom in modifying their regulations and, various options exist for them in formulating their national legislation to ensure a proper balance between the goal of providing incentives for future inventions of new drugs and the goal of affordable access to existing medicines.

Feature of the agreement-

1. **Standards-** The agreement set forth minimum standard for protection to be provided by each member country. Main element of the protection is defined; namely the subject-matter to be protected, right to be conferred and exception to those right and minimum duration of those rights.
2. **Enforcement-** secondly, TRIPS set forth the provision to deal with domestic procedure and remedies for enforcement of intellectual property. it lays down principle applicable to IPR enforcement procedure. In addition to that, it contain provision on civil and administrative procedure and remedies, provisional measure, criminal procedure, in certain detail, the procedure and remedies must be avialble so that right holder can effectively enforce his right.

3. **Dispute settlement-** Dispute settlement is through the dispute settlement system provided by WTO.

TRIPS set the minimum standard, which allow the member countries to provide more extensive protection, if they wish to. Member is free to determine the means to adopt the minimum standard laid down in TRIPS.

Preamble set forth the following principles-

1. Reducing distortions to international trade and promotion of adequate protection of intellectual property

The TRIPS aims at combating the counterfeit goods and distortions of international trade. The preamble recognizers that distortion may be caused by insufficient as well as excessive standard. While agreement defines, minimum standard but allow the member of WTO to adopt enhanced level of protection, the intention is to avoid barrier to legitimate trade by means of intellectual property protection.

2. Scope of new rules and disciplines

The preamble set forth the scope of regulation addressed by the agreement. It refer to the basic principle of non-discrimination, both newly applicable to the field (art4) and national treatment (art.3) as well as transparency (art 63)

3. Multilateral framework against trade in counterfeit goods

This reflects the main concern which drove the former GATT paties to elaborate a multilateral trade arrangement addressing the protection of IPR.

4. Private rights

TRIPS agreement recognizes intellectual property right as private right, pertaining to natural and juridical person. It implies that agreement essentially protect holder of intellectual property rights, as opposed to member. It depict the nature of right grnated, it grants holder the right to exclude third private party from commercially exploiting the subject matter protected by such rights commensurate with the definition of scope of rights ascribed to the different form of rights.

Patent and TRIPS

Section 5 of the TRIPS deals with the patenting. Some of the key provision included are-

1. Article 27.1- Article 27.1 provide protection to all the invention whatever sector of technology, subject to the exemption provided under art. 27.2 and 27.3 and tranational privileges for developing countries. Such patent shall be provided for product and process, subject to the test of novelty, inventive step(non-obviouness) and industrial application. Further, it provide that patent right should be enjoyable without discrimination as to place of invention, field of technology.
2. Article 27.2- it provide exception to the patenting. The invention can be exempted from patenting on the ground of ordre public or morality, it explicitly include invention dangerous to human, animal or plant life or health or serious prejudice to the environment. This exception is subjected to the condition that the commercial exfoliation of invention must also be prevented.
3. Article 27(3).(A)- it provide for exclusion of plant and animal other than micro-organism and biological process for the production of plants or animal other than non biological and microbiological processes.. Diagnostic, therapeutic and surgical method for the treatment of human and animal.
4. Article 28- it state the right granted to a patent holder. As per article 28 if its a product patent, the owner has right to prevent third parties from making using, offering for sale, selling or importing for these purposes that without his or her consent. Process patent protection must give rights not only over use of the process but also over products obtained directly by the process. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.[130]
5. Article 29.1- article 29 deal with disclosure of information. It require the patentee to disclose the invention clearly and completely.
6. Article 30- It state the exception to rights conferred. As per article 30, member countries can provide exception to the exclusive right conferred by a patent, provided this exception are not in conflict
7. Article 33- It state term of protection. As per this provision the term of protection shall not end before the expiration of a period of 20 years from the filing date.

[130] https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

8. Article 34- it state the process patents. as per article 34 if subject-matter of patent is process, the judicial authority has the authority to order the defendant to prove that process to obtain the patented product is different from patented process.
9. Article 31 allows the compulsory licensing and use without the authorization of the right holder. But subject to condition provided.

International Treaties and Patent law

Paris convention for the Protection of Industrial Property, 1883

It was adopted in 1883. The convention has been revised multiple time last in 1967 at Stockholm.[131] The convention is applicable to industrial property which include patents, trademark, service mark, industrial design, utility model, trade names, indication of source , appellations of origin and repression of unfair competition. The paris convention confer basic right known as right to national treatment and establishes another basic right known as right to priority.

1. National Treatment

Paris convention provides that each contracting state must grant same protecting to nationals of other contracting state as it provide to its own nationals.[132] In other words, nationals of non-contracting states are also entitled to national treatment under the convention if they are domiciled or have a real and effective industrial or commercial establishment in a contrating state. It prohibits two set of rules for the protection of industrial application one for nationals and other foreigners.

2. Right of Priority

Convention provide for right to priority in the case of patent, marks and industrial design. The right of priority means , on the basis of a regular first application filed in one of the contracting states, the applicant can within a certain period of time (12 month for patent and 6 month for industrial design and marks) apply for protection in any other contracting states. These application filed will have priority over application which may have been filed during

[131] V.K. Ahuja, Law relating to Intellectual property Rights, Lexis Nexis Butterworth
[132] Paris Convention, http://www.wipo.int/treaties/en/ip/paris/summary_paris.html

the said period of time by other person for the same invention. the advantage of this provision is that applicant has time period of 6 or 12 month to decise in which countries he/she want to seek protection.

The convention lays down some of the common rules

1. **Patent-** if a patent is granted for same invention in different contracting state, the same invention will be independent of each other. Granting of patent in one contracting state does not oblige other contracting state to grant a patent. A patent cannot be refused, annulled or terminated because it has been refused, annulled or terminated in any other contracting country. Further, each contracting state shall provide for measure to grant compulsory licensing.

Patent Cooperation Treaty

It is a special agreement under the Paris convention. PCT it has made it possible to seek patent protection for invention in large number of countries by filing an international patent application. Such application can be filed by the resident of the contracting state and is filed with the patent office of the contracting state or with International Bureau of WIPO in Geneva. Filling an PCT application, has the effect of automatically designating all contracting state bound by PCT on international filing date. The international application has the same effect as it has when application is filed at national patent office.

The international application is subjected to an international search. That search is carried out by one of the competent International Searching Authorities (ISA) under the PCT [1] and results in an international search report, that is, a listing of the citations of published documents that might affect the patentability of the invention claimed in the international application. In addition, a preliminary and non-binding written opinion on whether the invention appears to meet patentability criteria in light of the search report results is also issued.[133]

Patent Law Treaty

The patent Law treaty aims to accord and streamline formal method in admiration of national and regional patent application, thus to make it applicant friendly. With the noteworthy

[133] http://www.wipo.int/treaties/en/registration/pct/summary_pct.html

exemption of documenting date prerequisites, the PLT gives, maximum set of requisites which office of contracting party shall apply. This implies that a Contracting Party is allowed to adapt prerequisites that are more liberal from the perspective of candidate and holders, yet that the necessities under the PLT are required as to the greatest an office can require from candidates or managers. The Treaty contains, specifically, procurements on the accompanying issues:

Prerequisites for getting a filing date were standardise keeping in mind the end goal to minimize the dangers that candidates could coincidentally lose the recording date, which is of most extreme significance in the patent technique. The PLT obliges that the workplace of any Contracting Party must accord a documenting date to an application upon consistence with three straightforward formal prerequisites:

First and foremost, an evidence that the components got by the workplace are planned to be an application for a patent for a creation;

Second, evidences that would permit the workplace to recognize or to contact the candidate (then again, a Contracting Party is permitted to oblige signs on both);

Third, a part which seems, by all accounts, to be a depiction of the development.

No extra components can be needed for agreeing a recording date. Specifically, a Contracting Party can exclude one or more claims or a recording charge in a documenting date prerequisite. As said over, these prerequisites are not greatest necessities however constitute total prerequisites, so a Contracting Party would not be permitted to accord a documenting date unless each one of those necessities are consented to.

An arrangement of formal prerequisites for national and local applications was institutionalized by joining into the PLT the necessities identifying with structure or substance of worldwide applications under the PCT, including the substance of the PCT solicitation Form and the utilization of that demand Form joined by a sign that the application is to be dealt with as a national application.

The institutionalized Model International Forms that must be acknowledged by the workplaces of all Contracting Parties were secured.

Various methodology before patent workplaces were rearranged, which adds to a decrease in expenses for candidates and additionally for workplaces. Cases of such techniques are exemptions from obligatory representation, the limitation on obliging confirmation on an orderly premise etc.

The PLT gives strategies to maintaining a strategic distance from the inadvertent loss of substantive rights coming about because of inability to conform to convention necessities or time limits. These incorporate the commitment that workplaces advise the candidate or other concerned individual, expansions of time cutoff points, kept preparing, restoration of rights, and confinements on repudiation/nullification of a patent for formal deformities, where they were not perceived by the workplace amid the application stage.

The execution of electronic recording is encouraged, while guaranteeing the concurrence of both paper and electronic interchanges. The PLT gives that Contracting Parties were permitted to avoid paper correspondences and to completely change to electronic interchanges as of June 2, 2005. In any case, even after that date, they need to acknowledge paper correspondences with the end goal of acquiring a documenting date and for meeting a period limit.

The PLT was deduced in 2000, and went into power in 2005.

Budapest treaty on the International Recognition of the Deposit of Microorganisms for purpose of Patent Procedure

This convention is applicable for the invention which involve microorganism or use of a microorganism, disclosure of invention for patenting is not possible in writing but can be seeks only after deposit of sample of microorganism with a specialised institute.

The main feature of the treaty is that contracting state require the deposit of microorganism for the purpose of patent procedure must recognize for such purpose deposit of microorganism with the international depositry authority.[134]

A 'Depository authority' is a scientific institution- typically a culture collection which is capable of storing microorganism. Such an institute acquires the status of international depository authority on assurance being furnished furnishing by contracting state in the territory of which it is located.

Nagoya protocol on access to genetic resources and equitable sharing of benefits, 2010

The objective of this protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including appropriate access to genetic resource and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and sustainable use of its components.[135]

The Nagoya Protocol applies to genetic resources that are covered by the CBD, and to the benefits arising from their utilization. The Nagoya Protocol also covers traditional knowledge (TK) associated with genetic resources that are covered by the CBD and the benefits arising from its utilization.[136]

Article 5 of the protocol provides for benefit sharing arising from the use of genetic resources as well as subsequent application and commercialisation. The sharing must be fair and equitable. Parties are at liberty to determine what constitute such sharing according to thei needs through mutually agreed terms. Countries may stipulate minimum terms that ought to be included to fulfil the fair and equitable criteria in their nation law. Specific obligation to support compliance with domestic legislation or regulatory requirement of the party providing genetic resources and contractual obligations reflected in mutually agreed terms are significant innovation of the protocol. these compliance provisions as well as provisions establishing more predictable condition for access to genetic resources will contribute to ensuring the sharing benefits when genetic resources leaves the party providing genetic resources

[134] http://www.wipo.int/treaties/en/registration/budapest/
[135] Nagoya Protocol
[136] about Nagoya protocol, http://www.cbd.int/abs/about/, last accessed on 2nd April, 2015

Conclusion

Intellectual property is governed by many treaties and international organs. The aim objective of all the treaties and the origination is to promote the IPR and uniformity in all IPR laws of the world. Further, TRIPS has provided the minimum standards for the protection of every IPR right. Further many trieties have been passed addressing the emerging issue under different field.

Under treaties like PCT, Budapest treaty has been passed so as to address the emerging issues. But these treaties have not been able to address each and every issue. Issue for the patenting of nanotechnology has been addressed neither through TRIPS nor by any treaty. There are many other field of IPR which have not been addressed by the international community.

So, need of the hour is the to come up with treaties so as the address the emerging issue.

Chapter 6 :- Conclusion

Innovation is the driving force of the market. All the industry are indulge in invention one or other technology so as to become a market leader. Lot of time, efforts and invested to develop such technology. Like Ford was one of the first automobile industry to develop five gear car, which helped it to become a market leader. Further, google become leader in market by the introducing the anroid version mobile. Now, every company has adopted to remain in the market. This invention has not only helped google to earn profit but has also helped the US economy to grow. All the companies whether Samsung, micromax, Lenovo all run on anorid. This depicts the Vitol role invention plays to become a leader in market. Further, these invention are mostly develop through the intellectual labour of the person, team or a company, who dedicate their time and effort to develop such invention.

Invention is the driving force of the world. Such invention can be in form of some creative work like a story of movie like Avenger, one of its kind or it can be in form of song or a logo or design or a technology. All these invention involve the application of mind and time and effort. To encourage such inventions and to protect the time and efforts invested, unauthorised use company try to seek protection of such invention rather the time and efforts under the IPR.

Intellectual property is the creation of mind, human intellect. It is kind of asset like movable and immovable property, and can be sold, licensed, mortgaged exchanged like other form of property. Ownership of IPR is source of national wealth and mark of economic leadership, as the invention can be further licensed or assigned in return for royalty

Such intellectual property can be broadly be divide into two part – 1. Copyright and its right 2. Industrial property. Industrial property includes much other right like patent, trademark, industrial design, plant varities, geographical indication etc.

All the Innovation is protected under the Patent, a kind of industrial property. but before such innovation is protected, the term innovation has to be defined. There is no specific definition of innovation. It has been defined differently under domestic statue of the country. Besides definition there are many other essentials that need to be fulfilled before a patent is granted. TRIPS under section 5 has laid down condition before patent should be granted. Such condition are novelty, non-obviousness, industrial application. The term innventiomn has been broadly defined under the US law, as the Congree under the definition of Invention has

included discovery and improvement to already existing composite of matter, process, machine etc. whereas India and UK has a narrow definition of the invention it only include the invention which are new, neither discovery nor any improvement to the already existing machine, process etc.

The requirement of novelty is that the invention should be new in the sense that it does not form part of prior art. Prior art is the already existing knowledge on the subject matter claimed for patent. Such information can be in any form whether in written or in oral form. And the information available all over the world is taken into consideration. In simple word it should be an addition to the already existing knowledge on the subject matter.

Further, as per the condition of non-obviousness, the invention should not be obvious for the person skilled in the field in which the invention is claimed. It is question of fact and is decided objectively. All the relevant condition are taken into consideration to test the requirement of non-obviousness.

Last requirement of before is the patent is granted is that of industrial application. It other word the invention should be such it should be capable of being used in industry, has an utility should not be in abstract form or merely theoretical.

Before patent is granted all such condition need to be fulfilled as they depict one or the other feature of an invention. even the degree of these condition varies from country to country. US have relaxed criteria as compared to other countries. In India, the patent office is strict in the sense, that the statutory requirement under the act is strict for example new invention is considered when it is technically advance or has an economic significance. What is an invention has an economic significance only, will it be granted protection? Because as per provision ‘or is used not and so, will be invention will be granted or not jury is still out on it.

UK law has same system as that of India. But, the degree of requirement under the act varies.

Hence, for India it is time for amending the act, so as to make it Innovation friendly and to attract more foreign investor and to make the definition of Invention wide as the law of US has. Because if India had the same definition of as that of US the Novartis would has not gone for litigation.

Further, Nanotechnology is one of the growing industry around the world. There is no specific definition of nanotechnology. It has been defined as the application of technology at

small scale. In other words, it application of technology at nano scale. It is multi-disciplinary field, like sports, food, fashion etc. Like other industry, companies indulge in nanotechnology seek innovation and invest lot of money, time and efforts.

But patenting of nanotechnology is not easy task. Besides fulfilling the basis condition of novelty, inventive step and industrial application, there are many other issue involved. Firstly, their is no specific definition of nanotechnology, so it can be determined easily what is nanotechnology. Secondly, it is multi disciplinary field so an invention under nanotechnology can be claimed in different field. Thirdly, what constitute invention is difficult to determine, whether merely reduction in size constitute invention or there should be something novel. All this issue has made the patenting of nano-technology more difficult. Despite these, shortcoming US has highest number of patent in the field of nanotechnology

Biotechnology, is another emerging industry. The term biotechnology has been defined differently by the different author. There is no uniform definition of the biotechnology, it simplest term it can be defined as the synergy of technology and science. In other words, it is the application of technology on the bio material like genes, plants, animals, DNA etc.

Patenting of the biotechnology it has been controversial all over the world, due to involvement of bio-technology. In other words, most the invention under biotechnology involves life forms in one form or the other. So, it becomes difficult for the patent office to grant the patent to such form.

Further, patenting under the biotechnology has been critiqued many organisation around the world. The issue involved are- whether it is discovery or invention is not clear, this issue always arises before the patenting of genetic resources. As these resources are naturally occurring, merely identification of gene that it causes a particular disease should be regarded as the discovery not invention. as it was already in existence but has come to human knowledge, by identification by an individual. But the dispute has been settled by the court, and it is regarded as invention. Further, the issue of morality and ethics is also involved. Morality and ethics has been accepted as ground for rejection of the patent in much country like US, UK, and India. Moreover, TRIPS under article 27 provide for rejection of patent on the ground of morality. Because of this ground the cloning has been prohibited, which otherwise would have proved to be very useful in the development of

organs and would have saved many life. Only microorganism are granted patent, subject to the condition that the it should have some feature which were not naturally present in it.

Further, the transgenic animal are not granted patent but the transgenic plant are granted. India, has adopted a sui-generics system for patent of plant varities.

For pharmaceutical company, seeking a patent is a big challenged especially when they form a new medicine by merely combining known salt or substance or compound. In another words, merely combining the known substance. Such a combination would have been granted patent in US but in India, it is not granted, famous Novartas case is the example of this.

International framework governing the IPR is two main bodies WIPO and the WTO. WTO because it has an agreement of TRIPS attached to it. TRIPS has played a significant role in the development of the IPR all over the world. It lays down the minimum standard for the protection for the IPR and has left it to the discretion of the countries to adopt a high standard. Further, under TRIPS different section has been dedicated to each kind of intellectual property right. Section 5 of the TRIPS has been dedicated to the patent. Under it provide what all kind of invention are patentable and what are the exception to it and for which term protection should be granted to it.

TRIPS also provide for dispute settlement mechanism and also for enforcement of the intellectual property rights.

Further, on patent there some specific treaties on it like PCT which provide for filling of a patent application which is acceptable all over the word. The Budapest treaty which has made the pateting of microorganism easy by making a deposition of the sample at the institute. Further, the patent law treaty has also made the patenting more easily.

Hence, the innovation which has been driving force of the market, is protected efficiently is most part of the world, but their is still legislative vacuum for the emerging industry which need to be addressed. Moreover, the international body like WIPO and TRIPS should make the necessary recommendation to the member countries, so as to adapt to the dynamic environment of the emerging industry.

Recommendation

1. The definition of the term invention should be broaden so as, to cover maximum invention under it. like the US has the definition of invention, the same should be adopted by the US it will not only attract the foreign investment but will also boost the economy.

2. For patenting the requirement of the novelty, non-obviousness and industrial application should be relaxed to an extent. Even if an invention which will lead to increase in life cycle of a technology or is of economic significance should be considered for the invention.

3. For the patenting of the Nanotechnology a separate class should be formed, like Nano Patents. further, if an invention has a multi disciplinary application it should be made that claim to which an invention will have most beneficial use claim should be made in that field.

4. For biotechnology, patenting of invention which lead to organs should be accepted, it would lead to saving many life. Further, all the invention of life form should be made patentable except humans, only if it has utility in form or the other.

5. The International body should address the emerging issue in different industry like nanotechnology and biotechnology. TRIPS should further suggest to it member country how this issue should be dealt, with as every country has

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